

Ophthalmoscope, AC-powered Product code: HLI			
COMPANY	PRODUCT	FDA STATUS*	APPROVAL DATE
ACCUTECH MEDICAL TECHNOLOGIES INC.	TALIA RETINAL THICKNESS ANALYZER	Registered	n/a
ALCON LABORATORIES	ALCON INDIRECT OPHTHALMOSCOPE	SE	8/10/1982
AMERICAN MEDICAL OPTICS	AMER. MEDICAL OPTIC MONOCULAR DIRECT OPHTHALMASCOPE	SE	5/1/1985
AMERICAN MEDICAL OPTICS	AMER. MEDICAL OPTICAL BINOCULAR INDIRECT OPHTHALMA	SE	4/30/1985
AMERICAN MEDICAL OPTICS	AMER. MEDICAL OPTICS MONOCULAR INDIRECT OPHTHALMAS	SE	5/1/1985
BIOPTIGEN INC.	BIOPTIGEN SPECTRAL DOMAIN OPHTHALMIC IMAGING SYSTEM	SE	12/13/2006
BIOPTIGEN INC.	OPHTHALMOSCOPE, AC-POWERED (NOT SPECIFIED)	Registered	n/a
CANON U.S.A. INC.	CANON LASER BLOOD FLOWMETER (CLBF) MODEL 100	SE	6/21/2000
CANON U.S.A. INC.	CANON AUTO KERATOMETER K-1	SE	12/19/1984
CARL ZEISS INC.	HUMPHREY OCT SCANNER	SE	6/21/1996
CARL ZEISS INC.	ZEISS CONFOCAL LASER SCANNING OPHTHALMOSCOPE(CLSO)	SE	12/23/1991
CARL ZEISS MEDITEC INC	VISANTE OCT	SE	9/30/2005
CARL ZEISS MEDITEC INC	STRATUSOCT WITH RNFL NORMATIVE DATABASE	SE	5/1/2003
CARL ZEISS MEDITEC INC	CIRRUS HD-OCT MODEL 4000	SE	1/26/2007
CARL ZEISS MEDITEC INC	STRATUSOCT WITH RNFL & MACULA NORMATIVE DATABASE	SE	4/20/2004
CARLZEISS MEDITEC INC.	NERVE FIBER ANALYZER	SE	7/18/1994
CARLZEISS MEDITEC INC.	TOPOGRAPHIC SCANNING SYSTEM TOPSS	SE	3/26/1993
CARLZEISS MEDITEC INC.	ANGIOSCAN (AS STAND ALONE INSTRUMENT)	SE	6/26/1995
CARL ZEISS MEDITEC INC.	STRATUS OCT	Registered	n/a
CARL ZEISS MEDITEC INC.	CIRRUS HD OCT	Registered	n/a
CARL ZEISS MEDITEC INC.	STRATUS OCT	Registered	n/a
CARL ZEISS MEDITEC INC.	VISANTE OCT	Registered	n/a
CARL ZEISS MEDITEC INC.	GDx VCC; GDxPRO	Registered	n/a
CARL ZEISS MEDITEC INC.	STRATUS OCT	Registered	n/a
CARL ZEISS MEDITEC INC.	GDx WITH ECC RNFL NORMATIVE DATABASE	Registered	n/a
CENTERVUE	MAIA	Registered	n/a
CLEMENT CLARKE INC.	PROFESSIONAL INDIRECT OPHTHALMOSCOPE	SE	10/23/1991
EOL INC.	EOL MODEL LIO	SE	9/6/1988

SE: Substantially equivalent; Premarket notification, 501(k)

G. RODENSTOCK INSTRUMENTE GMBH	RODENSTOCK SCANNING LASER OPHTHALMOSCOPE	SE	6/10/1987
HAI LABORATORIES INC.	CLINICAL SPECULAR MICROSCOPE MODEL HAI CL-1000XYZ	SE	9/20/2000
HAI LABORATORIES INC.	CL-1000eva; CL-1000xyz	Registered	n/a
HEIDELBERG ENGINEERING	RETINA TOMOGRAPH AND FLOWMETER	SE	11/14/1994
HEIDELBERG ENGINEERING	HEIDELBERG RETINA ANGIOGRAPH FA/ICGA (HRA/C)	SE	7/29/1997
HEIDELBERG ENGINEERING	RETINA ANGIOGRAPH	SE	11/14/1994
HEIDELBERG ENGINEERING	HEIDELBERG RETINA TOMOGRAPH	SE	9/27/1991
HEIDELBERG ENGINEERING	RETINA FLOWMETER	SE	11/14/1994
HEIDELBERG ENGINEERING	HEIDELBERG RETINA ANGIOGRAPH	Registered	n/a
HEIDELBERG ENGINEERING	HEIDELBERG RETINA FLOWMETER; HRF	Registered	n/a
HEIDELBERG ENGINEERING	FA/ICGA; HEIDELBERG RETINA ANGIOGRAPH	Registered	n/a
HEIDELBERG ENGINEERING	HEIDELBERG RETINA TOMOGRAPH	Registered	n/a
HEIDELBERG ENGINEERING	and FLOWMETER; HEIDELBERG RETINA TOMOGRAPH	Registered	n/a
HEINE OPTOTECHNIK GMBH & CO. KG.	DIRECT OR INDIRECT OPHTHALMOSCOPES; HANDHELD INDIRECT OPHTHALMOSCOPE; K180; MONOCULAR, BINOCULAR; VARIOUS MODELS OF BETA; VARIOUS MODELS OF OMEGA; VARIOUS MODELS OF SIGMA	Registered	n/a
HGM MEDICAL LASER SYSTEMS INC.	LITESPOT(TM) LASER INDIRECT OPHTHALMOSCOPE	SE	1/6/1992
JEDMED INSTRUMENT CO.	OPHTHALMOSCOPE W-A	Registered	n/a
KEELER INSTRUMENTS INC.	VANTAGE INDIRECT OPHTHALMOSCOPE	SE	5/23/2006
KEELER INSTRUMENTS INC.	VISTA SPECIALIST OPHTHALMOSCOPE (BATTERY & AC)	SE	6/5/1989
KEELER INSTRUMENTS INC.	KEELER KONAN SPECULAR MICROSCOPE SP3300	SE	3/23/1990
KEELER INSTRUMENTS INC.	KEELER VANTAGE INDIRECT OPHTHALMOSCOPE	SE	8/4/1994
KEELER INSTRUMENTS INC.	THE KEELER ALL PUPIL INDIRECT OPHTHALMOSCOPE	SE	11/12/1985
KEELER INSTRUMENTS INC.	VISTA OPHTHALMOSCOPE (BATTERY AND AC-POWERED)	SE	6/5/1989
KEELER LTD.	VANTAGE INDIRECT OPHTHALMOSCOPE	Registered	n/a
KEELER LTD.	VANTAGE PLUS LED DIGITAL; VANTAGE PLUS LED WIRED; VANTAGE PLUS LED WIRELESS; VANTAGE PLUS WIRED; VANTAGE PLUS WIRELESS	Registered	n/a
KEELER LTD.	PRACTIONER DIRECT OPHTHALMOSCOPE; PROFESSIONAL DIRECT OPHTHALMOSCOPE; VISTA 20 DIRECT OPHTHALMOSCOPE	Registered	n/a
KEELER LTD.	SPECIALIST DIRECT OPHTHALMOSCOPE; VISTA SPECIALIST DIRECT OPHTHALMOSCOPE	Registered	n/a

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KEELER LTD.	FISION BINOCULAR INDIRECT OPHTHALMOSCOPE	Registered	n/a
KEELER LTD.	ALL PUPIL II (WIRED AND WIRELESS)	Registered	n/a
MEDICAL INSTRUMENT RESEARCH ASSOC. INC.	BLUE FIELD ENTOPTOSCOPE BFE100	SE	12/11/1979
MENTOR O & O INC.	MENTOR SPECTACLE BINOCULAR INDIRECT OPHTHALMOSCOPE	SE	9/11/1989
MENTOR O & O INC.	BINOCULAR INDIRECT OPHTHALMOSCOPE	SE	11/21/1984
MIRA INC.	SCHEPENS-YOSHIDA VIDEO BINOCULAR INDIRECT OPHTHALMSCOPE	SE	3/19/1997
MIRA INC.	OPHTHALMOSCOPE, AC-POWERED (NOT SPECIFIED)	Registered	n/a
NEITZ INSTRUMENTS COMPANY LTD.	NEITZ HALOGEN BINOCULAR INDIRECT OPHTHALMOSCOPE IO-A	SE	8/5/1994
NEITZ INSTRUMENTS COMPANY LTD.	NEITZ HALOGEN OPHTHALMOSCOPE BX-12	SE	8/5/1994
NEITZ INSTRUMENTS COMPANY LTD.	NEITZ HALOGEN OPHTHALMOSCOPE BX-RP	SE	8/5/1994
NEITZ INSTRUMENTS COMPANY LTD.	NEITZ HALOGEN OPHTHALMOSCOPE BX-123	SE	8/5/1994
NEITZ INSTRUMENTS COMPANY LTD.	NEITZ HALOGEN BINOCULAR INDIRECT OPHTHALMOSCOPE IO-H	SE	8/5/1994
NEITZ INSTRUMENTS COMPANY LTD.	NEITZ HALOGEN OPHTHALMOSCOPE BX-RC	SE	8/5/1994
NEITZ INSTRUMENTS COMPANY LTD.	INDIRECT OPHTHALMOSCOPE VIDEO SYSTEM IOO A TV	SE	4/7/1995
NIDEK INC.	MONOCULAR DIRECT OPHTHALMOSCOPE	SE	2/15/1985
NIDEK INC.	NIDEK-BINOCULAR INDIRECT OPHTHALMOSCOPE	SE	2/15/1985
NIDEK INC.	NIDEK MONOCULAR INDIRECT OPHTHALMOSCOPE	SE	2/15/1985
ODYSSEY OPTICAL SYSTEMS LLC.	S2LO	SE	8/5/1998
OKADA CORP.	MAMIYA SLIT LAMP P-1	SE	11/21/1984
OPHTHALMIC IMAGING SYSTEMS	GLAUCOMA-SCOPE	SE	10/9/1991
OPHTHALMIC IMAGING SYSTEMS	DSLII; WINSTATION RETINAL IMAGER	Registered	n/a
OPHTHALMIC TECHNOLOGIES INC.	OCT-OPHTHALMOSCOPE	SE	1/21/2005
OPTICAL IMAGING LTD.	RETINAL FUNCTIONAL IMAGER (RFI)	Registered	n/a
OPTOC INC.	PANORAMIC	Registered	n/a
OPTOS PLC	PANORAMIC200 OPHTHALMOSCOPE	SE	2/3/1999
OPTOS PLC	PANORAMIC 200A	SE	10/7/2004
OPTOS PLC	PANORAMIC	Registered	n/a
OPTOVUE INC.	R T VUE WITH SOFTWARE 5.0 MODEL: R I VUE 100	SE	6/17/2010
R & D BATTERIES INC.	R&D BATTERIES # 5615 5234 5097	SE	2/22/1994
REGALTECH PTY. LTD.	REGALTECH MAXISCOPE	SE	10/27/1992

SE: Substantially equivalent; Premarket notification, 501(k)

RODENSTOCK INSTRUMENT CORP.	RODENSTOCK SCANNING LASER OPHTHALMOSCOPE	SE	1/24/1989
TALIA TECHNOLOGY LTD.	RTA RETINAL THICKNESS ANALYZER	SE	2/3/1997
TALIA TECHNOLOGY LTD.	RTA MODEL D RETINAL THICKNESS ANALYZER	SE	5/24/2004
TALIA TECHNOLOGY LTD.	MODIFICATION TO RTA RETINAL THICKNESS ANALYZER	SE	3/31/2000
TALIA TECHNOLOGY LTD.	RTA 5 & RTA MODEL E RETINAL THICKNESS ANALYZER	SE	8/23/2006
TALIA TECHNOLOGY LTD.	RTA MODEL D RETINAL THICKNESS ANALYZER	SE	5/6/2003
VARIAN ASSOC. INC.	OPHTHALMOSCOPE BINOCULAR INDIRECT	SE	12/13/1977
WELCH ALLYN INC.	WELCH ALLYN 11800 OPHTHALMOSCOPE	SE	1/25/2001
WELCH ALLYN INC.	MODEL #12000 BINOCULAR INDERECT OPHTHALMOSCOPE	SE	6/21/1993
WELCH ALLYN INC.	WELCH ALLYN OPHTHALMOSCOPE	SE	4/4/1995
WELCH ALLYN INC.	WELCH ALLYN VIDEO OPHTHALMOSCOPE	SE	6/6/1995
WELCH ALLYN INC.	OPHTHALMOSCOPE MODEL #11100	SE	5/6/1977
WELCH ALLYN INC.	COMPACSET; DIAGNOSTICS SET; KLINIC; OPHTHALMOSCOPES, VARIOUS MODELS	Registered	n/a
WELCH ALLYN INC.	WELCH ALLYN 1100 OPHTHALMOSCOPE; WELCH ALLYN 11800 OPHTHALMOSCOPE	Registered	n/a
WELCH ALLYN INC.	POCKETSCOPE	Registered	n/a
WELCH ALLYN INC.	"BIO"; BINOCULAR INDIRECT OPHTHALMOSCOPE	Registered	n/a
WELCH ALLYN LTD.	WELCH ALLYN 1100 OPHTHALMOSCOPE; WELCH ALLYN 11800 OPHTHALMOSCOPE	Registered	n/a
WOODLYN INC.	WOODLYN SLIT LAMP HSSL-EC	SE	8/2/1984
WOODLYN INC.	WOODLYN CLASSIC KERATOMETER	SE	8/7/1984
WOODLYN INC.	WOODLYN CLASSIC CATARACT ACUITY TEST	SE	12/11/1984
WOODLYN INC.	WOODLYN CLASSIC JAVAL OPHTHALMOMETER	SE	8/7/1984
WOODLYN INC.	WOODLYN CLASSIC SLIT LAMP HSSL-CL	SE	8/7/1984

Ophthalmoscope, Battery-powered Product code: HLJ			
COMPANY	PRODUCT	FDA STATUS*	APPROVAL DATE
ACCESS / GOD LOVES YOU	MEDICAL BATTERY PACKS	SE	9/30/1992
ACCESS BATTERY LLC	MEDICAL BATTERY PACKS	Registered	n/a

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ALEXANDER MFG. CO.	MS401097-17MS722-KMS720MS721MS722	SE	7/3/1997
AUSTRALIAN BIOMEDICAL CORPORATION LTD.	VOROSCOPE(TM)	SE	6/3/1987
CARL ZEISS INC.	INDIRECT OPHTHALMOSCOPE	SE	10/4/1985
CARL ZEISS MEDITEC AG	OPHTHALMOSCOPE, BATTERY-POWERED (NOT SPECIFIED)	Registered	n/a
CERAMOPTEC INC.	MIS	SE	3/29/1993
CODMAN & SHURTLEFF INC.	SOLA COMMIDO LOUPE	SE	10/15/1976
CODMAN & SHURTLEFF INC.	SOLA SCHULTZE-CROCK OPHTHALMOSCOPE	SE	10/15/1976
DESIGN MED. CORP.	POCKET OPHTHALMOSCOPE GH	SE	11/27/1984
DESIGN MED. CORP.	#SM-3001 OPHTHA OTOSC SET SUBSETS SOLD	SE	9/6/1985
DESIGN MED. CORP.	MODEL BX OPHTHALMOSCOPE(BX-RP INCLUDES BATTE HAN)	SE	6/18/1985
GOVAL INTERNACIONAL S.A. DE C.V.	OPHTHALMOSCOPE, BATTERY-POWERED (NOT SPECIFIED)	Registered	n/a
GOWLLANDS MEDICAL DEVICES LTD.	OPHTHALMOSCOPE, BATTERY-POWERED (NOT SPECIFIED)	Registered	n/a
HEINE OPTOTECHNIK GMBH & CO. KG.	ALPHA; BETA; DIRECT OR INDIRECT OPHTHALMOSCOPES; K180; MINI; OMEGA; SIGMA	Registered	n/a
JEDMED INSTRUMENT CO.	DORC LIGHTWEIGHT BINOCULAR OPHTHALMOSCOP	SE	3/9/1983
KEELER INSTRUMENTS INC.	MEDIC LUX DIAGNOSTIC SETS	SE	8/16/1983
KEELER INSTRUMENTS INC.	KEELER WIDE ANGLE OPHTHALMOSCOPE MODEL 1130-P-5004	SE	11/26/2003
KEELER INSTRUMENTS INC.	KEELER SPECTRA INDIRECT OPHTHALMOSCOPE	SE	4/2/1997
KEELER LTD.	VANTAGE INDIRECT OPHTHALMOSCOPE	Registered	n/a
KEELER LTD.	VANTAGE PLUS LED DIGITAL; VANTAGE PLUS LED WIRED; VANTAGE PLUS LED WIRELESS; VANTAGE PLUS WIRED; VANTAGE PLUS WIRELESS	Registered	n/a
KEELER LTD.	WIDE ANGLE OPHTHALMOSCOPE	Registered	n/a
KEELER LTD.	SPECTRA OPHTHALMOSCOPE; SPECTRA PLUS OPHTHALMOSCOPE	Registered	n/a
KELLER INSTRUMENTS INC.	SPECTACLE INDIRECT OPHTHALMOSCOPE	SE	5/9/1984
KIRCHNER & WILHELM GMBH + CO.KG	PICCOLIGHT E50PICCOLIGHT E56EUROLIGHT E10 EUROLIGHT E30 AND EUROLIGHT E36	SE	11/5/2007
KIRCHNER & WILHELM GMBH + CO.KG	OPHTHALMOSCOPE, BATTERY-POWERED (NOT SPECIFIED)	Registered	n/a
LACRIMEDICS INC.	FOCOMETER	SE	11/22/1994
MAGNA FORTIS CORPORATION	MAGNA FORTIS OPHTHALMOSCOPE DIAGNOSTIC KIT	SE	9/12/2000
NEITZ INSTRUMENTS COMPANY LTD.	NEITZ HALOGEN POCKET OPHTHALMOSCOPE A-JR	SE	8/5/1994

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NEITZ INSTRUMENTS COMPANY LTD.	HALOGEN OPHTHALMO-OTOSCOPE SET BX A - 134	SE	3/28/1995
NEITZ INSTRUMENTS COMPANY LTD.	HALOGEN DIAGNOSTIC SET BX A - 12345	SE	3/22/1995
NEITZ INSTRUMENTS COMPANY LTD.	NEITZ HALOGEN OPHTHALMOSCOPE BXA-13A	SE	8/5/1994
NEITZ INSTRUMENTS COMPANY LTD.	NEITZ HALOGEN OPHTHALMOSCOPE BXA-13	SE	8/5/1994
NORTH AMERICAN MEDICAL PRODUCTS INC.	D.L. SCOPE OPHTHALMOSCOPE	SE	11/27/1989
NORTH AMERICAN RESCUE LLC.	ENT DIAGNOSTIC CONVENIENCE KIT	Registered	n/a
OPHTHALMOS LTD.	OPTYSE OPHTHALMOSCOPE	SE	5/16/2006
OPHTHALMOS LTD.	OPTYSE LENS FREE OPHTHALMOSCOPE	Registered	n/a
PRECISION OPTICS CORP.	PRECISION OPTICS CORPORATION VIDEO OPHTHALMOSCOPE MODEL 2500-VOS	SE	1/9/2006
PRECISION OPTICS CORP.	MODEL 2500-V05; POC VIDEO	Registered	n/a
R & D BATTERIES INC.	R & D BATTERIES	SE	2/22/1994
R & D BATTERIES INC.	R&D BATTERIES PART NOS. 5135 5097 5444 AND 5502	SE	6/3/1994
R & D BATTERIES INC.	REPLACEMENT BATTERIES PART NO. 50985135 5097	SE	2/22/1994
RANDWAL INSTRUMENT CO. INC.	PORTABLE ACUIOMETER	SE	8/15/1984
RANDWAL INSTRUMENT CO. INC.	IRAS GLARE TESTER	SE	11/24/1987
RUDOLF RIESTER GMBH & CO. KG	RI-FORMER	SE	10/15/1993
RUDOLF RIESTER GMBH & CO. KG	OPHTHALMOSCOPE	SE	8/3/1993
RUDOLF RIESTER GMBH & CO. KG	RI-FORMER WALL MODEL 25 V/220 V OR 110 V 35 V/220 V OR 110 V RI-FORMER ANAESTHETIC MODEL 25 V/220 V OR 110 C 35 V/V	SE	7/24/1995
RUDOLF RIESTER GMBH & CO. KG	RI-SCOPE S OTOSCOPE	SE	1/17/1995
RUDOLF RIESTER GMBH & CO. KG	UNI II	SE	10/18/1993
RUDOLF RIESTER GMBH & CO. KG	DE LUXE	SE	12/3/1993
RUDOLF RIESTER GMBH	MULTIPLE	Registered	n/a
RUDOLF RIESTER GMBH	UNI II	Registered	n/a
RUDOLF RIESTER GMBH	RI-FORMER	Registered	n/a
SHANGHAI SEEI MEDICAL SCI-TECH. CO. LTD.	OPHTHALMOSCOPE, BATTERY-POWERED (NOT SPECIFIED)	Registered	n/a
SHANGHAI SEEI MEDICAL SCI-TECH. CO. LTD.	OPHTHALMOSCOPE, BATTERY-POWERED (NOT SPECIFIED)	Registered	n/a

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SUZHOU 66 VISION TECH CO. LTD.	66 VISION TECH OPHTHALMOSCOPE MODELS YZ6E YZ6F YZ6G YZ11 YZ11C YZ11D YZ25A	SE	11/7/2006
SUZHOU 66 VISION TECH CO. LTD.	66 VISION TECH OPHTHALMOSCOPE	Registered	n/a
TRUPHATEK LTD.	ORIEL	SE	7/9/1992
VISUAL METHODS INC.	EYESCOPE	SE	4/10/1978
VOLK OPTICAL INC.	OPHTHALMOSCOPE - RI MINI; OPHTHALMOSCOPE L2	Registered	n/a
WELCH ALLYN INC.	WELCH ALLYN 1100 OPHTHALMOSCOPE; WELCH ALLYN 11800 OPHTHALMOSCOPE	Registered	n/a
WELCH ALLYN LTD.	WELCH ALLYN 1100 OPHTHALMOSCOPE; WELCH ALLYN 11800 OPHTHALMOSCOPE	Registered	n/a

Ophthalmoscope, Laser, Scanning Product code: MYC			
COMPANY	PRODUCT	FDA STATUS*	APPROVAL DATE
CARL ZEISS MEDITEC INC	GDXPRO	SE	11/25/2009
CARL ZEISS MEDITEC INC.	GDX VCC WITH ECC SOFTWARE	SE	8/10/2009
CARL ZEISS MEDITEC INC.	GDx WITH ECC RNFL NORMATIVE DATABASE	Registered	n/a
CARL ZEISS MEDITEC INC.	GDxPRO MODEL 8000	Registered	n/a
KOWA CO. LTD.	KOWA FM-600 MODEL LSS50	SE	8/7/2009
KOWA CO. LTD.	KOWA FM-600	Registered	n/a
NIDEK CO. LTD.	OPHTHALMOSCOPE F-10	SE	5/6/2008
NIDEK CO. LTD. HAMACHO PLANT	OPHTHALMOSCOPE F-10	Registered	n/a
OPTOS INC	PANORAMIC	Registered	n/a
OPTOS PLC	PANORAMIC MODEL 200MA	SE	3/17/2006
OPTOS PLC	OPTOS LIMITED PANORAMIC 200CAF	SE	7/15/2010
OPTOS PLC	PANORAMIC 200CAF	Registered	n/a

Ophthalmoscope, Replacement batteries, Hand-held Product code: MSG			
COMPANY	PRODUCT	FDA STATUS*	APPROVAL DATE

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ALEXANDER MFG. CO.	ALEXANDER MANUFACTURING CO. RECHARGEABLE BATTERY PART NUMBER MS721-P	SE	5/6/1997
ALEXANDER MFG. CO.	ALEXANDER MANUFACTURING COMPANY PRCHARGEABLE BATTERY	SE	3/31/1997

Retinoscope, AC-powered Product code: HKL			
COMPANY	PRODUCT	FDA STATUS*	APPROVAL DATE
CMT MEDICAL TECHNOLOGIES LTD.	PANORET MODEL 1000A	SE	7/7/2000
HAGG-STREIT SERVICE INC.	MOIRE FRINGE VISOMETER AFTER LOTMAR	SE	3/10/1980
HEINE OPTOTECHNIK GMBH & CO. KG.	HEINE BETA 200® SPOT RETINOSCOPE; HEINE BETA 200® STREAK RETINOSCOPE	Registered	n/a
KEELER INSTRUMENTS INC.	VISTA STREAK RETINOSCOPE (AC-POWERED)	SE	9/21/1989
KEELER LTD.	PROFESSIONAL COMBI RETINOSCOPE; VISTA STREAK RETINOSCOPE	Registered	n/a
KOI INC.	KOI BLUE FIELD ENTOPTOSCOPE	SE	12/2/1981
NEITZ INSTRUMENTS COMPANY LTD.	STREAK RETINOSCOPE RX-1	SE	3/28/1995
NEITZ INSTRUMENTS COMPANY LTD.	STREAK RETINOSCOPE RX-2	SE	3/22/1995

Retinoscope, Battery-powered Product code: HKM			
COMPANY	PRODUCT	FDA STATUS*	APPROVAL DATE
APPASAMY ASSOCIATES	RETINOSCOPE, BATTERY-POWERED (NOT SPECIFIED)	Registered	n/a
APPASAMY ASSOCIATES	RETINOSCOPE, BATTERY-POWERED (NOT SPECIFIED)	Registered	n/a
APPASAMY ASSOCIATES	RETINOSCOPE, BATTERY-POWERED (NOT SPECIFIED)	Registered	n/a
ELECTRO OPTICAL INSTRUMENTS	GENERATED RETINAL REFLEX IMAGERY SYS	SE	7/12/1984
HEINE OPTOTECHNIK GMBH & CO. KG.	HEINE ALPHA+® SPOT RETINOSCOPE; HEINE ALPHA+® STREAK RETINOSCOPE; HEINE BETA 200® SPOT RETINOSCOPE; HEINE BETA 200® STREAK RETINOSCOPE	Registered	n/a
JEDMED INSTRUMENT CO.	BATTERY-POWERED; RETINOSCOPE	Registered	n/a
LIANYUNGANG TIANNUO OPTICAL INSTRUMENT CO. LTD.	RETINOSCOPE	Registered	n/a

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NEITZ INSTRUMENTS COMPANY LTD.	SPOT RETINOSCOPE RX-3SP	SE	3/28/1995
NEITZ INSTRUMENTS COMPANY LTD.	STREAK RETINOSCOPE RX-3	SE	3/28/1995
NEITZ INSTRUMENTS COMPANY LTD.	STREAK RETINOSCOPE RX-RP	SE	3/28/1995
NEITZ INSTRUMENTS COMPANY LTD.	STREAK RETINOSCOPE RX-RC	SE	3/28/1995
NEITZ INSTRUMENTS COMPANY LTD.	STREAK RETINOSCOPE RX-3A	SE	3/28/1995
NEITZ INSTRUMENTS COMPANY LTD.	MULTIPLE	Registered	n/a
RAY VISION INTL CORP.	RETINOSCOPE, BATTERY-POWERED (NOT SPECIFIED)	Registered	n/a
RUDOLF RIESTER GMBH & CO. KG	RI-TINISCOPE-SLIT/RI-TINISCOPE SPOT/RI-VISION-SLIT/RI-VISION-SPOT	SE	1/9/1997
RUDOLF RIESTER GMBH	RI-SCOPE RETINOSCOPE; RI-VISION RETINOSCOPE	Registered	n/a
STALLION MEDICAL INC.	STREAK AND SPOT RETINOSCOPE	Registered	n/a
TAIYUAN XIN YUAN HIGH TECH CENTER	RETINOSCOPE, BATTERY-POWERED (NOT SPECIFIED)	Registered	n/a
UNICOS USA LLC	SEVERAL MODELS, VLR-18200; STREAK RETINOSCOPE COMPLETE SET	Registered	n/a
VISION RESEARCH CORP.	YISISCREEN OSS-C	Registered	n/a
WELCH ALLYN INC.	STREAK AND SPOT RETINOSCOPES	Registered	n/a
ZUMAX MEDICAL CO LTD.	STREAK RETINOSCOPES	Registered	n/a

Tomography, Optical Coherence Product code: OBO			
COMPANY	PRODUCT	FDA STATUS*	APPROVAL DATE
CARL ZEISS MEDITEC INC	CIRRUS HD-OCT WITH RETINAL NERVE FIBER LAYER AND MACULAR NORMATIVE DATABASES MODEL 4000	SE	5/5/2009
CARL ZEISS MEDITEC INC	CIRRUS HD-OCT MODEL 400; CIRRUS HD-OCT wRNFL & MNDB	Registered	n/a
HEIDELBERG ENGINEERING	HEIDELBERG RETINA ANGIOGRAPH 2/OPTICAL COHERENCE TOMOGRAPH MODEL HRA 2/OCT	SE	10/31/2006
HEIDELBERG ENGINEERING	SPECTRALIS HRA-OCT	Registered	n/a
OPKO HEALTH INC.	SPECTRAL OCT/SLO	SE	11/14/2008
OPKO INSTRUMENTATION	SPECTRAL OCT/SLO	Registered	n/a
OPTOVUE INC.	RTVUE	SE	10/6/2006
OPTOVUE INC.	IVUE MODEL 100	SE	4/22/2010
OPTOVUE INC.	CA MODEL: CAM	SE	9/28/2007
OPTOVUE INC.	RTVUE	Registered	n/a

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OPTOVUE INC.	iVUE; iVUE 100; iVUE100	Registered	n/a
OPTOVUE INC.	iVUE; iVUE 101	Registered	n/a
REICHERT INC.	SOCT COPERNICUS MODEL 15205	SE	2/27/2008
TOPCON CORP.	TOPCON 3D OCT-1000 OPTICAL COHERENCE TOMOGRAPHY SYSTEM	SE	6/22/2007
TOPCON CORP.	OPTICAL COHERENCE TOMOGRAPHY 3D OCT-2000	SE	9/2/2009
TOPCON CORP.	3D OCT-1000; OPTICAL COHERENCE TOMOGRAPHY SYSTEM	Registered	n/a
TOPCON CORP.	3D OCT-1000 MARK II; OPTICAL COHERENCE TOMOGRAPHY SYSTEM	Registered	n/a
TOPCON CORP.	3D OCT-2000; OPTICAL COHERENCE TOMOGRAPHY SYSTEM	Registered	n/a
TOPCON CORP.	3D OCT-1000	Registered	n/a
TOPCON MEDICAL SYSTEMS INC.	3D OCT-1000 MARK II OPTICAL COHERENCE TOMOGRAPHY SYSTEM	SE	3/13/2009
TOPCON MEDICAL SYSTEMS INC.	TOPCON 3D OCT-1000 OPTICAL COHERENCE TOMOGRAPHY SYSTEM FOR MEASUREMENT OF RETINAL THICKNESS	SE	1/13/2009

Tonometer, AC-powered Product code: HKX			
COMPANY	PRODUCT	FDA STATUS*	APPROVAL DATE
ACCUTOME ULTRASOUND INC.	ACCUPEN	SE	7/27/2009
ACCUTOME ULTRASOUND INC.	ACCUPEN	Registered	n/a
AMERICAN OPTICAL CORP.	AO NON-CONTACT II TONOMETER	SE	11/12/1980
AMERITEK INC.	SURGICAL IOP MONITOR	SE	9/25/1986
BIO-RAD	TIP & MEMBRANE ASSEMBLY	SE	6/22/1993
BIO-RAD	DIGILAB MODULAR ONE-APPLANATION TONOMETER	SE	9/24/1986
BIO-RAD	DIGILAB MICRO ONE APPLANATION TONOMETER	SE	2/20/1987
BIO-RAD	CYLINDER OF GAS CAN OF GAS (CC12F2)	SE	8/5/1992
BIO-RAD	BIO-RAD MODULAR AIR COMPRESSOR	SE	10/31/1989
CANON COMPONENTS INC.	TX-F	Registered	n/a
CANON INC.	NON-CONTACT TONOMETER T-2	SE	5/12/1995
CANON INC.-MEDICAL EQUIPMENT GROUP	TX-F	Registered	n/a
CANON INC.-UTSUNOMIYA OPTICAL PRODUCTS OPERATION	CANON FULL AUTO TONOMETER TX-F	SE	11/26/2002

SE: Substantially equivalent; Premarket notification, 501(k)

CANON U.S.A. INC.	CANON TX-10 TONOMETER	SE	3/3/1997
CDS TECHNOLOGIES	ZEIMER SELF TONOMETER	SE	8/22/1995
COOPERVISION INC.	CLERZ LUBRICATING/REWETTING SOLUTION	SE	1/4/1984
COOPERVISION INC.	CAT 100	SE	6/19/1984
EYETECH LLC.	EPISCLERAL VENOUS PRESSURE	SE	11/19/1984
ICARE FINLAND OY	ICARE; ICARE TONOMETER	Registered	n/a
INAMI & CO. LTD.	TONOMETER, AC-POWERED (NOT SPECIFIED)	Registered	n/a
KEELER INSTRUMENTS INC.	KEELER PULSAIR NON CONTACT TONOMETER MODIFICATION	SE	6/25/1991
KEELER INSTRUMENTS INC.	KEELER PULSAIR NON CONTACT TONOMETER	SE	3/17/1987
KEELER INSTRUMENTS INC.	KEELER PULSAIR 3000 NON CONTACT TONOMETER	SE	3/25/1999
KEELER LTD.	PULSAIR 3000 NON CONTACT TONOMETER; PULSAIR EASYEYE NON CONTACT TONOMTE	Registered	n/a
KOWA CO. LTD.	KOWA KT-800	SE	6/9/2006
KOWA CO. LTD.	KOWA AUTOMATED TONOMETER KT-500	Registered	n/a
KOWA CO. LTD.	KOWA KT-800	Registered	n/a
KOWA OPTIMED INC.	KOWA AUTOMATED TONOMETER KT-500	SE	10/11/2002
KRB ENT.	T P C (TONOMETER PROBE COVER)	SE	6/3/1987
LANGHAM OPHTHALMIC TECHNOLOGIES	LANGHAM OCULAR BLOOD FLOW (OBF) TONOGRAPH/TONOMETER MODEL 201	SE	6/27/2001
LEICA MICROSYSTEMS INC.	LEICA AT550	SE	6/7/1999
LEICA MICROSYSTEMS INC. O.I.D.	PORTABLE NON-CONTACT TONOMETER MODEL PT100	SE	2/20/2002
NIDEK INC.	NON-CONTACT TONOMETER MODEL NT-4000	SE	12/4/2003
NIDEK INC.	NIDEK MODEL NT-1000	SE	10/15/1991
NIDEK CO. LTD. HAMACHO PLANT	NON-CONTACT TONOMETER; NT-4000; NT-510; NT-530	Registered	n/a
OCULAR BLOOD FLOW LABORATORIES INC.	OBF MODEL 112 VACUUM CUP SYSTEM	SE	2/12/1987
OCULAR BLOOD FLOW LABORATORIES INC.	OBF MODEL 115 COMPUTER TONOMETER SYSTEM	SE	11/2/1987
ODC OPHTHALMIC DEVELOPMENT CO. AG	SMARTLENS	SE	10/18/2000
OPTICAL RADIATION CORP.	COMPUTON(R)	SE	9/3/1986

SE: Substantially equivalent; Premarket notification, 501(k)

OPTILASA S.L.	APPLANATION TONOMETER	SE	4/24/2003
OPTILASA	TONOMETER, AC-POWERED (NOT SPECIFIED)	Registered	n/a
OPTI-MED ELECTRONICS	DIGITAL AVERAGING TONOMETER	SE	8/17/1995
OPTIMETRICS INC.	TONOMETER	Registered	n/a
PROFESSIONAL TECHNOLOGIES CORP.	MMAC II TONOMETER	SE	1/6/1989
R.H. BURTON CO.	BURTON APPLANATION TONOMETER - MODEL T850 & T1000	SE	4/5/1993
REICHERT INC.	NON-CONTACT TONOMETERS OCULAR RESPONSE ANALYZER	SE	1/20/2004
REICHERT INC.	OCULAR RESPONSE ANALYZER	SE	8/7/2008
REICHERT INC.	PT100	Registered	n/a
REICHERT INC.	AT550; AT555; REICHERT 7; REICHERT 7CR	Registered	n/a
REICHERT INC.	OCULAR RESPONSE ANALYZER	Registered	n/a
REICHERT INC.	ATP; MULTIPLE	Registered	n/a
REICHERT INC.	MODEL 30 CLASSIC PNEUMATONOMETER	Registered	n/a
REICHERT INC.	TIP & MEMBRANE ASSEMBLY	Registered	n/a
REICHERT OPHTHALMIC INSTRUMENTS DIV. LEICA INC.	XPERT NCT	SE	9/29/1994
RETINAPHARMA TECHNOLOGIES INC.	TONOPACH ULTRASONIC TONOMETER/PACHYMETER MODEL P-201 (THE TONOPACH)	SE	12/10/2004
RICHMOND PRODUCTS INC.	TONOMETER TAPES	SE	11/2/1987
RYAZAN STATE INSTRUMENTS	TONOMETER DIATON	SE	4/6/2006
RYAZAN STATE INSTRUMENT-MAKING ENTERPRISE	DIATON TONOMETER	Registered	n/a
SONOMETRICS SYSTEMS INC.	GLAUKON	SE	4/9/1982
SPAN-AMERICA MEDICAL SYSTEMS INC.	SPAN-AID BRIDGING PILLOW SYSTEM	SE	8/4/1980
TOMEY CORPORATION	NON-CONTACT TONOMETER MODEL FT-1000	SE	11/18/2008
TOMEY CORPORATION	NON-CONTACT TONOMETER MODEL FT-1000	Registered	n/a
TOPCON INSTRUMENT CORPORATION OF AMERICA	TOPCON COMPUTERIZED TONOMETER CT-10	SE	5/18/1987
TOPCON CORP.	CT-80	Registered	n/a
TRUEVISION INSTRUMENTS	TGDC-01 PRA	SE	10/11/2002
VISIONCARE DEVICES INC.	TONOMETER PROBE	Registered	n/a

SE: Substantially equivalent; Premarket notification, 501(k)

WOODLYN INC.	WOODLYN APPLANATION TONOMETER	SE	8/2/1984
XOMED INC.	MODEL 30 CLASSIC PNEUMATONOMETER	SE	12/11/2000

Tonometer, Manual Product code: HKY			
COMPANY	PRODUCT	FDA STATUS*	APPROVAL DATE
AUTOMATED OPHTHALMICS INC.	AUTOMATED OPHTHALMICS SOFTIPS	SE	1/10/2000
AUTOMATED OPHTHALMICS INC.	ACCUTIP COVER; SOFTIPS TONOPEN TIPCOVER	Registered	n/a
BAUSCH & LOMB INC.	PROVIEW EYE PRESSURE MONITOR	SE	7/2/2001
BERNARD B. FRESCO	FRESCO PHOSPHENE TONOMETER AND OR PHOSPHENE TONOMETER AND OR FPT AND OR EYELID TONOMETER	SE	3/20/2000
BOBES S.A.	BOBES TONOMETER	SE	6/20/1995
BOBES S.A.	APPLANATION TONOMETER	Registered	n/a
C.S.O. S.R.L.	F 900	SE	8/6/2002
C.S.O. S.R.L.	TONOMETER, Z800	Registered	n/a
C.S.O. S.R.L.	A900, F900	Registered	n/a
CAREFUSION 2200 INC.	TONOMETER, MANUAL (NOT SPECIFIED)	Registered	n/a
CAREFUSION GERMANY 206 GMBH	TONOMETER, MANUAL (NOT SPECIFIED)	Registered	n/a
CLEMENT CLARKE INC.	PERKINS HAND-HELD APPLANATION TONOMETER	SE	7/18/1996
CONPHAR INC.	CONPHAR-SCHIOETZ TONOMETER	SE	2/24/1982
CSO	C.S.O. TONOMETER	SE	6/6/2000
DIGILAB INC.	OCULAR CEREBRAL VASCULAR MONITOR	SE	11/28/1977
EYE-DEAS LLC	EYESOPEN TONOMETER	SE	9/23/2003
FALCK MEDICAL INC.	FALCK APPLANATION TONOMETER (FAT2)	SE	6/3/2008
FALCK MEDICAL CORPORATION	FALCK MEDICAL TONOMETERS; FAT2, FAT1	Registered	n/a
GERHARD BIRO	BIRO SCHIOETZ-TONOMETER	Registered	n/a
GOLDEN VISION INC.	GOLDMAN MANUAL TONOMETER	SE	1/12/1999
HAAG STREIT UK LTD.	PERKINS APPLANATION TONOMETER; TONOSAFE	Registered	n/a
HAAG STREIT AG	PERKINS APPLANATION TONOMETER	Registered	n/a
HEINE OPTOTECHNIK GMBH & CO. KG.	GLAUCO TEST; TONOMETER, MANUAL	Registered	n/a
ICAL INC.	TONOMETER DIGITON	SE	9/27/1978

SE: Substantially equivalent; Premarket notification, 501(k)

ICARE FINLAND OY	ICARE; ICARE TONOMETER	Registered	n/a
IMM ENTERPRISES LTD.	JAKOBI SURG. INSTRUMENTS #6 50	SE	3/5/1984
INSTRUMED INTERNATIONAL INC.	MULTIPLE	Registered	n/a
KATENA PRODUCTS INC.	SCHIOTZ TONOMETER	Registered	n/a
KEELER LTD.	KEELER APPLANATION TONOMETER; T-TYPE KAT K-TYPE KAT (KAT)	SE	1/19/2010
KEELER LTD.	KAT - APPLANATION TONOMETER T TYPE	Registered	n/a
KOWA CO. LTD.	KOWA APPLANATION TONOMETER HA-1; KOWA APPLANATION TONOMETER HA-2	Registered	n/a
KOWA OPTIMED INC.	KOWA HAND-HELD APPLANATION TONOMETER HA-1	SE	6/4/1996
LUNEAU SA	LUNEAU STERILE TONOMETER SEPARATION PRISMS	SE	2/20/2003
LUNEAU SAS	LUNEAU TONOMETER SEPARATION PRISMS	Registered	n/a
MED-TECH DEVELOPMENT CORP.	MAKLAKOV STYLE TONOMETER	SE	2/12/1986
MEDTRONIC XOMED INC.	TONO-PEN AVIA TONOMETER AND OCU-SHILED TIP COVER	SE	3/3/2006
MENTOR OPHTHALMICS INC.	MENTOR TONO-PEN 3	SE	11/26/1996
MIAMI EYE TECHNOLOGY INC.	SURGICAL IOP MONITOR	SE	11/28/1983
MILTEX GMBH	MADER TONOMETERS; MILTEX TONOMETER	Registered	n/a
MILTEX INC.	MADER TONOMETERS; MILTEX TONOMETER	Registered	n/a
OASIS MEDICAL INC.	TONOSHIELD TONOMETER SHIELD	SE	9/30/1992
OCULAB INC.	OCULAB TONOPEN	SE	8/20/1985
OCULAB INC.	OCU-FILM TIP COVER	SE	8/4/1988
PARADIGM MEDICAL INDUSTRIES INC.	BLOOD FLOW ANALYZER	SE	6/17/1997
PROFOUND RUBBER IND SDN BHD	SOFT TIPS	Registered	n/a
REICHERT INC.	MODIFICATION TO: OCU-FILM TIP COVER	SE	3/27/2007
REICHERT INC.	TONO-PEN	Registered	n/a
REICHERT INC.	OCU-FILM TIP COVER	Registered	n/a
REICHERT INC.	TONO-PEN AVIA	Registered	n/a
REICHERT INC.	CT200; CT210	Registered	n/a
REICHERT INC.	OCU-FILM TIP COVER	Registered	n/a
REICHERT OPHTHALMIC INSTRUMENTS DIV. LEICA INC.	REICHERT CT200 CONTACT TONOMETER	SE	3/23/2000
RUDOLF RIESTER GMBH & CO. KG	SCHIOTZ TONOMETER SPEC. 5 STRAIGHT INCLINED 3INCLINED SCALE	SE	5/8/1995

SE: Substantially equivalent; Premarket notification, 501(k)

RUDOLF RIESTER GMBH	SCHIOTZ	Registered	n/a
RZ MEDIZINTECHNIK GMBH	TONOMETER, MANUAL (NOT SPECIFIED)	Registered	n/a
SMT SWISS MICROTECHNOLOGY AG	PASCAL DYNAMIC CONTOUR TONOMETER	SE	11/14/2003
SMT SWISS MICROTECHNOLOGY AG	MULTIPLE	Registered	n/a
STALLION MEDICAL INC.	MULTIPLE	Registered	n/a
TECNOLOGIA OPTICA INDUSTRIAL 3B S.L.	APPLANATION TONOMETER	Registered	n/a
TELEFLEX MEDICAL	MULTIPLE MANUAL TONOMETER; SCHIOTZ	Registered	n/a
TELEFLEX MEDICAL TUTTLINGEN GMBH	MULTIPLE MANUAL TONOMETER; SCHIOTZ	Registered	n/a
TIOLAT OY	ICARE TONOMETER TA01I	SE	5/23/2007
TOMEY CORPORATION USA	TOMEY PROTON TONOMETER	SE	4/5/1993
TRA & ACCESSORIES	TONO-PEN TONOMETER TIP COVER	SE	11/23/2004
WILSON OPHTHALMIC CORP.	TONOMETER, MANUAL (NOT SPECIFIED)	Registered	n/a
ZIEMER OPHTHALMIC SYSTEMS AG	MULTIPLE	Registered	n/a

Tonometer (Calibration and Q.C. of blood-gas instruments), Clinical Product code: LCH			
COMPANY	PRODUCT	FDA STATUS*	APPROVAL DATE
AMERICAN INSTRUMENT CO.	HEM-O-SCAN OXYGEN EQUIL. CURVE ANALYZER	SE	10/31/1980
ASSOCIATED MEDICAL REPRESENTATIVES	AMR RESEARCH TONOMETER	SE	11/24/1986
BIONOSTICS INC.	RNA MEDICAL TONOMETER	SE	6/26/1992
BIONOSTICS INC.	RNA MEDICAL TONOMETER	Registered	n/a
CORNING MEDICAL & SCIENTIFIC	CORNING 184 BLOOD GAS TONOMETER	SE	8/20/1980
CRYOGENIC RARE GAS LABORATORIES INC.	BLOOD GAS CALIBRATION STANDARD	SE	4/25/1990
EQUILIBRATED BIO SYSTEMS INC.	EBS 775 TONOMETER	SE	9/14/1978
LINEAR TONOMETERS INC.	LINEAR CLOUD TONOMETER	SE	5/22/1984
MEDICOR USA LTD.	PRECISION GAS MIXER	SE	9/20/1978
NORCO INC.	CLINICAL BLOOD GAS MIXTURES	SE	11/1/1990
NORCO INC.	TONOMETER, CLINICAL (NOT SPECIFIED)	Registered	n/a

SE: Substantially equivalent; Premarket notification, 501(k)

Perimeter, AC-powered Product code: HOO			
COMPANY	PRODUCT	FDA STATUS*	APPROVAL DATE
BIO-RAD	DIGILAB CAMBRIDGE PERIMETER	SE	2/27/1986
CARL ZEISS MEDITECH INC	FDT 7100; MATRIX 715	Registered	n/a
COOPERVISION INC.	AUTOMATIC TANGENT SCREEN 50	SE	9/29/1983
HARTEST PRECISION INSTRUMENTS LTD	HENSON5000; HENSON6000; HENSON6000+; HENSON7000; HENSON8000	Registered	n/a
KEELER INSTRUMENTS INC.	HENSON - HAMBLIN CFS 2000 CENTRAL FIELD SCREEN	SE	12/15/1986
MARCO OPHTHALMIC INC.	MARCO PROJECTION PERIMETER	SE	6/21/1993
MC ASSEMBLY AND TEST INC	PERIMETER, AC-POWERED (NOT SPECIFIED)	Registered	n/a
OCULUS OPTIKGERATE GMBH	TUBINGER PERIMETER	Registered	n/a
PARADIGM MEDICAL INDUSTRIES INC.	HENSON 6000 COMPACT	Registered	n/a
RICHMOND PRODUCTS INC.	RICHMOND VISUAL FIELD SCREENER	SE	11/2/1987
TAKAGI SEIKO CO. LTD.	PERIMETER MT-325UD	Registered	n/a
WELCH ALLYN INC.	WELCH ALLYN GLAUCOMA DETECTOR	SE	6/6/1994
WELCH ALLYN INC.	HUMPHREY VISUAL FIELD INSTRUMENT	Registered	n/a

Perimeter, Automatic, AC-powered Product code: HPT			
COMPANY	PRODUCT	FDA STATUS*	APPROVAL DATE
APPASAMY ASSOCIATES	PERIMETER, AUTOMATIC, AC-POWERED (NOT SPECIFIED)	Registered	n/a
BIO-RAD	DIGILAB 750 AUTOMATED PERIMETER W/IBM PERSON/COMPU	SE	3/4/1985
BIO-RAD	DIGILAB 350 THE KRAKAU PERIMETER	SE	8/16/1983
BIO-RAD	DIGILAB MODEL 1500 PERIMETER	SE	2/20/1987
CARL ZEISS INC.	HUMPHREY FIELD ANALYZER (HFA II)	SE	11/24/1995
CARL ZEISS MEDITEC INC	GUIDED PROGRESSION ANALYSIS ON THE HUMPHREY FIELD ANALYZER II AND II -I SERIES	SE	3/12/2010
CARL ZEISS MEDITEC INC	HFA (SERIES); HUMPHREY FIELD ANALYZER	Registered	n/a
CARL ZEISS MEDITEC INC	GUIDED PROGRESSION ANALYSIS-GPA FOR; HUMPHREY FIELD ANALYZER II & II-i	Registered	n/a

SE: Substantially equivalent; Premarket notification, 501(k)

CAVITRON CORP.	AUTO-FIELD D AUTOMATED VISUAL DETECTOR	SE	4/29/1980
CAVITRON CORP.	AUTO-FIELD II OPHTHALMIC FIELD SCANNER	SE	9/14/1978
CENTERVUE	MAIA	Registered	n/a
CENTERVUE SPA	MAIA MODEL 1	SE	5/27/2010
CILCO INC.	OCTOPUS 500/500E	SE	6/19/1984
CLEMENT CLARKE INC.	OPTICOM M600	SE	7/25/1994
COBURN OPTICAL IND. INC.	AUTOMATED PERIMETERS	SE	2/4/1981
COOPERVISION INC.	DICON GLAUCOMA DIAG. CENTER 2000 SERIES	SE	8/1/1983
DICON INC.	DICON AUTO PERIMETER 2000	SE	8/20/1981
DICON INC.	AUTO PERIOMETER 3000	SE	9/30/1982
DICON INC.	DICON AUTO PERIMETER 200	SE	8/20/1981
FREY SPOLKA JAWNA	OPTO PERIMETER	Registered	n/a
HAAG-STREIT AG	MULTIPLE	Registered	n/a
HITRON CORP.	OCTOPUS	SE	4/10/1978
KASHA SOFTWARE INC.	KASHA VISUAL FIELD SYSTEM	SE	5/28/1997
KETA CORP.	QUANTUM 412	SE	12/5/1984
KOWA CO. LTD.	KOWA AP-5000C	Registered	n/a
KOWA OPTIMED INC.	AUTOMATIC VISUAL FIELD PLOTTER AP-125	SE	6/17/1996
KOWA OPTIMED INC.	AUTOMATIC PERIMETER AP-340	SE	5/3/1988
LKC TECHNOLOGIES INC.	PATTERN DISCRIMINATION PERIMETER	SE	1/12/1988
LKC TECHNOLOGIES INC.	PDP-3000	Registered	n/a
LUMENIS INC.	PERIMETRON AUTOMATIC	Registered	n/a
MARCO OPHTHALMIC INC.	MS-30 AUTOMATIC PERIMETER	SE	7/27/1994
MARCO TECHNOLOGIES	MT-336 AUTOMATIC PERIMETER	SE	9/18/1990
MEDMONT INTERNATIONAL PTY LTD	MULTIPLE BRANDS OF MEDM	Registered	n/a
METROVISION SAS	MONCV3	Registered	n/a
NIDEK INC	PERIMETER	Registered	n/a
NIDEK TECHNOLOGIES SRL	RETINAL CAMERA	Registered	n/a
NIDEK TECHNOLOGIES SRL	PERIMETER	Registered	n/a
NIDEK TECHNOLOGIES SRL	MICROPERIMETER MP1	Registered	n/a

SE: Substantially equivalent; Premarket notification, 501(k)

NOTAL VISION INC.	THE NOTAL VISION PREVIEW PREFERENTIAL HYPERACUITY PERIMETER (PREVIEW PHP)	SE	4/29/2005
NOTAL VISION INC.	FORESEE HOME	Registered	n/a
NOTAL VISION LTD.	FORESEE HOME	SE	12/23/2009
NOTAL VISION LTD.	FORESEE HOME	Registered	n/a
NOVAVISION INC.	HMP-100	Registered	n/a
OCULUS OPTIKGERATE GMBH	MULTIPLE	Registered	n/a
OPTIKON OFTALMOLOGIA SPA	PERIKON PCL 90	SE	1/28/1993
OPTIMED INC.	OPTIFIELD I AND II AUTOMATED PERIMETERS	SE	3/9/1989
OPTIMED INC.	OPTIMED ADVANTAGE	SE	11/7/1988
OPTO ELETRONICA S.A.	OPTO AUTOMATED PERIMETER AP 100; OPTO AUTOMATED PERIMETER AP 200	Registered	n/a
OPTOPOL TECHNOLOGY S.A.	PERIMETER PTS 1000; PERIMETER PTS 910; PERIMETER PTS 910BY; VARIOUS NAMES AND MODELS	Registered	n/a
PARADIGM MEDICAL INDUSTRIES INC.	LD400 FT AUTOPERIMETER; TKS 4000 AND LD 400 AUTOPERIMETER; TKS 5000 FT AUTOPERIMETER	Registered	n/a
PRECISION TECHNOLOGY SERVICES LTD.	MULTIPLE BRANDS OF MEDM	Registered	n/a
REICHERT INC.	MULTIPLE	Registered	n/a
REICHERT INC.	FORESEE PHP	Registered	n/a
SCHIFF HARDING WAITE	BAYLOR VISUAL FIELDS PROGRAMMER	SE	8/10/1979
SEEING MACHINES LIMITED	TRUEFIELD ANALYZER	SE	8/2/2007
SEEING MACHINES LIMITED	TRUEFIELD ANALYZER	Registered	n/a
SHORASHIM	OCUMAP 100 AUTOPERIMETER	SE	2/10/1984
STALLION MEDICAL INC.	PERIMETER	Registered	n/a
SYNEMED INC.	FIELD TREND	SE	11/17/1995
SYNEMED INC.	MODEL 200 SQUID	SE	10/18/1982
SYNEMED INC.	THE FIELDMASTER MODEL 275	SE	10/15/1985
SYNEMED INC.	MULTIPLE	Registered	n/a
TECHNA VISION	TECHNA VISION AUTO-PERIMETER	SE	11/12/1985
VISIONRX LLC	GLAUCOMACHECK	Registered	n/a
VISMED INC.	TKS 4000 AUTO PERIMETER	SE	11/2/1987

SE: Substantially equivalent; Premarket notification, 501(k)

VISMED INC.	LD 400	SE	10/18/1993
WEST COAST OPTICAL INSTRUMENTS INC.	FIXATION MONITOR	SE	9/30/1982
YIZRAEL TAMUZ	PERIMETER, AUTOMATIC, AC-POWERED (NOT SPECIFIED)	Registered	n/a
ZEISS HUMPHREY SYSTEM	THE HUMPHREY FIELD ANALYZER MODEL 610	SE	7/28/1982
ZEISS HUMPHREY SYSTEM	HUMPHREY FIELD ANALYZER MODEL 630	SE	9/18/1985

Perimeter, Manual Product code: HON			
COMPANY	PRODUCT	FDA STATUS*	APPROVAL DATE
ACCUTOME INC.	ACCUTOME	Registered	n/a
APPASAMY ASSOCIATES	PERIMETER, MANUAL (NOT SPECIFIED)	Registered	n/a
INAMI & CO. LTD.	INAMI PROJECTION PERIMETER	Registered	n/a
MACULAR METRICS II LLC	MACULAR DENSITOMETER PERIMETER	Registered	n/a

* "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Listing of a medical device is not approval of the establishment or a device by FDA." FDA website

DEFINITIONS**Aqueous humor**

The fluid filling the front of the eye between the cornea and the lens. Aqueous is created by the ciliary body and drains out through Schlemm's canal via the trabecular meshwork.

Blindness

A visual acuity worse than 20/400, with the best possible correction, or a visual field of 10 degrees or less.

{World Health Organization}

Cataract

Opacification of the native crystalline lens. **Intraocular pressure** is a measurement of the fluid pressure inside the eye.

Deep Sclerectomy

A non-penetrating procedure involving near-full thickness dissection of sclera and peripheral cornea overlying Schlemm's canal. Fluid is allowed to percolate through Descemet's membrane into the subconjunctival space where it is resorbed.

Glaucoma

An optic neuropathy (optic nerve disease) with a characteristic appearance of the optic nerve and a characteristic loss of midperipheral vision.

Foster PJ, Buhrmann, R, Quigley HA, Johnson GJ. The definition and classification of glaucoma in prevalence surveys. *British Journal of Ophthalmology* 2002; 86: 238-242.

Glaucoma suspect

Individual who may have early, but not definitive glaucomatous optic nerve damage, or individual who does not have glaucomatous optic nerve damage, but for demographic reasons or ocular reasons has a high chance of developing glaucoma.

Foster PJ, Buhrmann, R, Quigley HA, Johnson GJ. The definition and classification of glaucoma in prevalence surveys. *British Journal of Ophthalmology* 2002; 86: 238-242.

Open Angle Glaucoma

A progressive optic neuropathy characterized by loss of retinal ganglion cells and "cupping" of the optic nerve. Glaucoma is defined to be of the open angle type when the anterior chamber angle is open on gonioscopic examination.

Glaucoma, Primary open angle

Open angle glaucoma in the absence of any other ocular, systemic or pharmacological cause and accompanied by elevated intraocular pressure

Glaucoma, Secondary

Glaucoma associated with raised intraocular pressure due to a recognized or systemic disease, or to a pharmacological treatment..

Glaucoma drainage device (also called a tube shunt)

A tube connected to a plate (or reservoir). The plate is secured to the sclera at or behind the equator of the eye and the tube is inserted into the anterior chamber. Aqueous then drains out of the eye to the plate where it is resorbed.

Low vision

Visual acuity between 20/70 and 20/400, with the best possible correction, or a visual field of 20 degrees or less. (ICD 9 definition)

Optic nerve

The bundle of nerve fibers that transmits visual information from the eye to the brain

Ophthalmologist

Medical doctor who is specialized in eye and vision care. Ophthalmologists are trained to provide the full spectrum of eye care.

Optometrist

Health care professional who is licensed to provide primary eye care services.

Perimetry

Systematic determination and mapping of the limits of the visual field, usually for the purpose of detecting anomalies in the visual pathway

Primary care physician

A generalist physician who provides definitive care to the undifferentiated patient at the point of first contact and takes continuing responsibility for providing the patient's care. Such a physician must be specifically trained to provide primary care services.

Patient-reported outcome or PRO is a questionnaire used in a clinical trial or a clinical setting, where the responses are collected directly from the patient

Tonometry

Measurement of intraocular pressure (IOP).

Trabeculoplasty

Photocoagulation of the trabecular meshwork of the eye by means of a laser.

Trabeculectomy

As currently practiced, a trabeculectomy is a full thickness (the surgical wound extends into the eye) filtering procedure with a partial-thickness scleral flap overlying it to regulate outflow of aqueous.

Non-Penetrating Surgery

Any of a number of procedures used to decrease intraocular pressure without creating a wound that extends the full thickness of the eye wall.

Viscocanalostomy

A type of non-penetrating surgery aimed at lowering intraocular pressure by manipulating Schlemm's canal. A scleral flap is dissected over Schlemm's canal and then a viscoelastic substance is injected. The superficial flap is then sutured in place at the end of the procedure.

Visual field

The area within which visible light stimuli can be detected by an eye in a straight-ahead position.

The Heidelberg Retina Tomograph (HRT) is a confocal laser scanning microscope. It uses multiple tomographic images to measure either the optic nerve head or posterior retinal structures to detect glaucomatous damage to the nerve fiber layer of the retina. It also detects non-glaucomatous retinal changes in the microstructure of the posterior retina (e.g., macular edema, atrophy associated with degenerative retinal diseases).

ABBREVIATIONS

AE	Adverse events
AHRQ	Agency for Health Related Quality
CAI	Carbonic anhidrase inhibitors
CCT	Central corneal thickness
CEA	Cost-effectiveness analysis
CI	Confidence interval
COAG	Chronic open angle glaucoma
EPC	Evidence-based Practice Center
FDA	Food and Drug Administration
GAT	Goldmann applanation tonometry
GRADE	Grading of Recommendation Assessment, Development and Evaluation
HRQL	Health related quality of life
HTA	Health technology assessment
HRT	Heidelberg retina tomography
IOP	Intraocular pressure
ITT	Intention to treat
MD	Mean deviation
OCT	Optical coherence tomography
OHT	Ocular hypertension
PGA	Prostaglandin analogs
PICO	Patient-Intervention-Comparators-Outcomes
POAG	Primary open angle glaucoma
PPA	Peri-papillary atrophy
PRO	Patient reported outcomes
QOL	Quality of life
RCT	Randomized controlled trial
RR	Relative risk
SAP	Standard automated perimetry
SD	Standard deviation
SLT	Selective laser trabeculoplasty
SR	Systematic review
VAS	Visual analogue scale
VF	Visual field