K012416

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
CONFOSCAN 2 CONFOCAL MICROSCOPE

SUBMITTER INFORMATION

A.	Company Name:	Nidek Technologies Srl
B.	Company Address:	Via Regina, 88 Vigonza (Padova), Italy 35010
C.	Company Phone: Company Fax:	39 49 89 35 191 39 49 62 55 84
D.	Contact Person:	Mr. Aldo Cocchiglia Managing Director Nidek Technologies Srl
E.	Date Summary Prepared:	October 24, 2001

DEVICE IDENTIFICATION

A.	Classification Name:	AC-Powered Slit-Lamp Biomicroscope
B.	Trade/Proprietary Name:	ConfoScan 2 Confocal Microscope
C.	Device Classification:	Class II (886.1850)
D.	Product Code:	HJO

DEVICE DESCRIPTION

The Nidek Technologies Srl ConfoScan 2 Confocal Microscope is a fully digital, corneal confocal microscope that allows a user to view and image human corneal layers *in vivo*. The confocal arrangement consists of one slit that illuminates the tissue and a second slit that filters the reflected light from unfocused layers. The user can view, magnify, measure, and photograph separate layers of the transparent structures and tissues of the cornea. One examination records 350 different images.

The ConfoScan 2 microscope is supplied with a Quartz Halogen light source and a scanning slit, suitable for performing ophthalmic examination. The system includes a 15-inch LCD S-VGA Monitor and a Personal Computer, which incorporates the dedicated NAVIS software.

INTENDED USE

The ConfoScan 2 Confocal Microscope is intended for use in the precise display and digital storage of images of the corneal layers (endothelium, descemet's membrane, stroma, bowman's membrane, and epithelium) and corneal components (endothelial cells, stromal keratocytes, nerve fibers, basalar and superficial cells). The microscope is also used for optical pachymetry, post-surgery interface evaluation, endothelial cell analysis, haze detection, foreign bodies, corneal dystrophies, keratoconus, keratitis, and trauma.

SUBSTANTIAL EQUIVALENCE

The ConfoScan 2 Confocal Microscope device has the same intended use and the same fundamental scientific technology as the following predicate device:

Predicate Device	510(k) Holder	510(k) No.	Date Cleared
ConfoScan Confocal Microscope	Tomey Corporation	K972953	August 14, 1997

TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the ConfoScan 2 Confocal Microscope and the predicate device has been performed, and the results are summarized in the table below. The results of this comparison demonstrate that the ConfoScan 2 Confocal

Microscope device has the same basic technological characteristics as the predicate device and is equivalent to the marketed predicate device.

CONFOCAL MICROSCOPE TECHNOLOGICAL COMPARISON		
	Nidek Technologies Srl ConfoScan 2 Confocal Microscope	**Tomey ConfoScan Confocal Microscope Predicate Device – K971953**
Indications For Use	The Nidek Technologies Srl Confoscan 2 Confocal Microscope is indicated for use as a diagnostic tool for observation of the cell layers of the anterior parts of the eye.	The Tomey Confoscan Confocal Microscope is indicated for use as a diagnostic tool for looking at the cell layers of the anterior parts of the eye.
Corneal Contact	In normal use the front surface of the eye does not contact the objective lens; however, corneal contact can occur. The ConfoScan 2 has an automatic sensing feature which detects if the cornea has been touched (a warning is sounded and the objective reverses direction).	In normal use the front surface of the eye does not contact the objective lens; however, corneal contact can occur.
Floating Objective Lens	Yes	Yes
Working Distance Between Cornea and Objective	1.98 mm	0 to 10 mm (depending on lens)
Focus	Fixed	Fixed
Adjustment Direction	The examination device is horizontally adjusted while the patient is sitting straight in front of the device (automatic or manual adjustment option).	The examination device is horizontally adjusted while the patient is sitting straight in front of the device (manual adjustment only).
Front Lens Area	$16.61mm^2$	$16.61mm^2$

CONFOCAL MICROSCOPE TECHNOLOGICAL COMPARISON		
	Nidek Technologies Srl ConfoScan 2 Confocal Microscope	**Tomey ConfoScan Confocal Microscope Predicate Device – K971953**
Type Scanning Aperture	Slit	Slit
Light Source	100W Halogen, Internal	100W Halogen, External
Objective Lens	Water Immersion Lens Achroplan 40x	Water Immersion Lens Achroplan 40x
Depth Resolution	10 microns	10 microns
Horizontal Resolution	1 micron	1 micron
Pre Sterilized Lens	No. Lens disinfected according to instructions for use.	No. Lens disinfected according to instructions for use.
Working Position	Horizontal	Horizontal
Standard Magnification	40x	40x
Mean Magnification	500x on 15" display (1024 x 768 pixels).	500x on 15" display (1024 x 768 pixels).
Numerical Aperture (na)	0.75	0.75
CCD Camera	Yes, (monochrome, 5 milliLux sensitivity)	Yes, (monochrome, 5 milliLux sensitivity)
Image Storage	Image directly stored in PC RAM, then saved to a PC hard drive	Image stored on VCR tape, then transferred to a PC
Automated Endothelial Cell Analysis Software	Yes, the program provides the user with a cell density (cells/mm^2).	Yes, the program provides the user with a cell density (cells/mm^2).
Optical Pathway	Typical confocal microscope optical path with IR and UV filters. Slit oscillation is controlled by a stepper motor.	Typical confocal microscope optical path with IR and UV filters. Conjugate Scanning slits with Galvin meter controls slit movement.
Physical Layout	The lift table, PC, and Optical head are integrated into one piece	The lift table, PC, and Optical head are three separate modules
Operating Software	NAVIS	Confo-Commander
Z-Scan Principle (Cornea Profile Measurement)	A CCD camera is used instead of the photo multiplier to record the scattered light from each corneal image. This value is calculated directly from the recorded image and placed within a profile curve. There is now an image correlated to each point on the curve.	An intensity profile is taken via the photo multiplier as a standing slit is scanned through the cornea. The Photo multiplier records scattered light profiles of the cornea. The values are then placed on a graph that provides the user with a profile curve of the cornea without a correlated image.

PERFORMANCE EVALUATION

The following testing was performed on the ConfoScan 2 Confocal Microscope to demonstrate that it meets all specified requirements and is equivalent to the predicate device:

A. Electrical Safety Testing & Electromagnetic Compatibility

The ConfoScan 2 Confocal Microscope was tested in accordance with EN 60601-1 and EN 60601-1-2, and was found to meet all requirements of both standards.

B. Programmable Electrical Medical Systems

The ConfoScan 2 Confocal Microscope was tested in accordance with EN 60601-1-4 and was found to meet all requirements of the standard.

C. Fundamental Test Requirements and Test Methods for Ophthalmic Instruments

The ConfoScan 2 Confocal Microscope was tested in accordance with ISO 15004 and was found to meet all requirements of the standard.

D. Light Energy Levels

The amount of light energy transferred to the patient during the normal examination time of one to two minutes was found to be negligible.

E. Endothelial Cell Analysis Software Validation

A total of 134 samples (extracted from corneal images) were analyzed by the ConfoScan 2 Confocal Microscope to validate the resulting automatic cell density

values via comparison to the results of two other commercially available specular microscopes.

CONCLUSIONS

Nidek Technologies Srl has demonstrated through its evaluation of the ConfoScan 2 Confocal Microscope that the device is equivalent to the predicate device with respect to intended use, technological characteristics, and safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 6 2001

NIDEK TECHNOLOGIES SRL
c/o Ms. Carol L. Patterson
Patterson Consulting Group, Inc.
21911 Erie Lane,
Lake Forest, CA 92630

Re: K012416
Trade/Device Name: ConfoScan 2 Confocal Microscope
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered Slip-Lamp Biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: July 27, 2001
Received: July 30, 2001

Dear Ms. Patterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE

510(k) Number: K012416 (To Be Assigned By FDA)

Device Trade Name: ConfoScan 2 Confocal Microscope

Indications For Use: The ConfoScan 2 Confocal Microscope is indicated for use as a diagnostic tool for observation of the cell layers of the anterior parts of the eye.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

Nancy C. Brogdon-Nichols

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K012416