



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 4 2004

Konan, Inc.
c/o George H. Myers, Sc.D.
Medsys Inc.
377 Route 17 South
Hasbrouck Heights, NJ 07604

Re: K980357

Trade/Device Name: Konan Noncon Robo Pachy Specular Microscope
Regulation Number: CFR 886.1850
Regulation Name: AC-powered slitlamp biomicroscope
Regulatory Class: Class II
Product Code: NQE
Dated: January 28, 1998
Received: January 29, 1998

Dear Dr. Myers:

This letter updates our substantially equivalent letter of April 24, 1998 regarding the product code and classification regulation of your device. Specular microscopes are now regulated under §886.1850 (AC-powered slitlamp biomicroscope) and are listed under a new product code (NQE). This letter is for informational purposes. No further action is required on your part at this time.

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 (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 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.

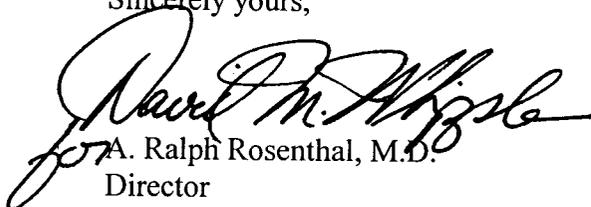
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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 continue 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 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. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



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

Enclosure

510(k) Number (if known): K980357

Device Name: Konon Noncon Robo Pachy

Indications for Use:

The Konon Noncon Robo Pachy is a specular microscope and optical pachymeter, manufactured by Konon Inc. It is a non-contact ophthalmic microscope and camera intended for examination of the corneal endothelium, with the additional capability of measuring the corneal thickness by optical means. Cell counting and analysis programs are included, and are indicated when it is desired to analyze the images of the cell distribution of the eye.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

E. M. Allen

(Division Sign-Off)

Division of Ophthalmic Devices

510(k) Number K980357

Prescription Use
(Per 21 CFR 810.109)

OR

Over-the-Counter Use

(Optional Format 1-2-96)

Konan Medical Inc.
Konan NonCon Robo Pachy
510(k) Submission

APR 24 1998

510(k) Summary

(1) Submitter Information

Name: Konan Inc.

Address: 10-29 Miyanishi-Cho
Nishimomiya
662 Japan

Telephone Number: 011-81-798363456

Contact Person: Dr. George Myers (Official Correspondent)
Medsys Inc.
377 Rt. 17 S
Hasbrouck Heights, NJ 07604
201-727-1703

Date Prepared: December 12, 1997

(2) Name of Device:

Trade Name: Konan NonCon Robo Pachy
Common Name: Specular Endothelial Microscope and Camera
and optical pachymeter
Classification Name: Camera, Ophthalmic, AC-powered

(3) Equivalent legally-marketed devices:

1. Konan Noncon Robo, K950091
2. DGH 2000 ultrasonic pachymeter, K920906

(4) Description

The Noncon Robo Pachy specular microscope and optical pachymeter is a non-contact ophthalmic microscope, optical pachymeter, and camera intended for examination of the corneal endothelium and for measurement of the thickness of the cornea. It is an improvement to the original Konan Noncon Robo, K950091.

The device permits visual inspection and photography of the corneal endothelium and measurement of the corneal thickness without any object contacting the eye. It features

focusing by means of infrared techniques, and computer-assisted cell counting and cell analysis capabilities. The computer functions are also used to aid in setting up the various features of the machine and to aid in photography. Photographic images are temporarily stored in the system's memory, and are preserved in video form on magnetic tape or by using a video printer. The memory can store two endothelial cell images and two anterior segment images, which are usually those of the left and right eyes.

(5) Intended Use

The Konan Noncon Robo Pachy is a specular microscope and optical pachymeter, manufactured by Konan Inc. It is a non-contact ophthalmic microscope and camera intended for examination of the corneal endothelium, with the additional capability of measuring the corneal thickness by optical means. Cell counting and analysis programs are included, and are indicated when it is desired to analyze the images of the cell distribution of the eye.

(6) Technological characteristics

The Konan Noncon Robo Pachy is technically the same as the predicate device, the Konan Noncon Robo, with the addition of more accurate sensors to provide sufficient accuracy for clinical pachymetry measurements. The original Noncon Robo, sold as a specular microscope, had the ability to measure corneal thickness, but the measurements were not accurate enough for clinical use. The "Pachy" version has more accurate sensors. The computer program that controls the system has been modified to permit display and control of the pachymeter feature.

(b) Performance data

(1) Non-clinical tests

The non-clinical tests done for the original Noncon Robo also apply to the Noncon Robo Pachy, since the device is essentially the same. A new software validation test has been done, to validate the new software. The system meets the requirements of the standards JIS T 1001-1988, Safety Code for Medical Devices, and JIS T 1002, General Rules of Testing Methods for Safety of Medical Electrical Equipment, and the standards of the EMC Directive 89/336/EEC. The original 510(k)

has the certificates and details on the tests. The bench test section has a Declaration of Conformity to the EEC tests. The accuracy of the pachymetry system has been established by tests on an accurately machined phantom, and are in the Bench Test Section.

(2) Clinical tests

Corneal thickness measurements made on 100 patients have been compared with measurements on the same patients using the DGH 2000 ultrasonic pachymeter. This test shows that the Noncon Robo Pachy gives at least an accuracy equivalent to the DGH 2000.

(3) Conclusions

The Konan Noncon Robo Pachy is equivalent in safety and efficacy to the legally marketed predicate devices.