K040373

MAR 19 2004

510(k) Submission
Konan Kerato Analyzer (EKA)
510(k) Summary
January 13, 2004

(1) Submitter Information

Name: Konan Medical Inc.

Address: 10-29 Miyanishi-Cho
Nishimomiya Hyogo
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: February 4, 2004

(2) Name of Device:

Trade Name: Konan Kerato Analyzer
Common Name: Specular Microscope for Eye Banks.
Classification Name: Camera, Ophthalmic, AC-powered

(3) Equivalent legally-marketed devices:

Konan Noncon Robo, K950091
Hai Labs EB2000 xyz, K994340

(4) Description

The Konan Kerato Analyzer ("EKA") is a specular microscope used to make cell counts of preserved corneas in eye banks and to measure the thicknesses of the corneas without removing the corneas from their storage vials.

(5) Intended Use

The Konan Kerato Analyzer ("EKA") is a intended to make cell counts of preserved corneas in eye banks without removing the corneas from their storage vials.

(6) Technological characteristics

The basic structure of the EKA is similar to that of an inverted laboratory microscope. With the EKA, all focusing is done manually by the operator; focusing is done automatically by the Noncon Robo. With the Noncon Robo, the patient looks into the device at a fixation target. For the EKA, vials containing the corneas are placed in a receptacle in the unit.

(b) Performance data

(1) Non-clinical tests

Cell counts on eye bank samples were done with the Noncon Robo and the EKA. Statistical analysis showed that the two devices gave the same counts.

(2) Clinical tests

Not required

(3) Conclusions

The Konan Kerato Analyzer is equivalent in safety and efficacy to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 2004

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

Re: K040373
Trade/Device Name: Konan Kerato Analyzer (EKA)
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered slitlamp biomicroscope
Regulatory Class: Class II
Product Code: NQE
Dated: February 10, 2004
Received: February 17, 2004

Dear Dr. Myers:

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), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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, 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): K040373

Device Name: Konon Kerato Analyzer

Indications for Use:

The Konan Kerato Analyzer ("EKA") is a specular microscope used to make cell counts of preserved corneas in eye banks and to measure the thicknesses of the corneas without removing the corneas from their storage vials.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K040373

Prescription Use ✓ **OR** **Over-the-Counter Use** ____
(Per 21 CFR 810.109)

(Optional Format 1-2-96)