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

510(k) Summary

(1) Submitter Information

Name: Konan Inc.

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Nishimomiya
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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: October 31, 2007

(2) Name of Device:

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

(3) Equivalent legally-marketed devices:

Konan Noncon Robo Pachy, K980357

(4) Description

The Noncon Robo Pachy F&A 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 Pachy, K980357.

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 F&A 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 F&A, with the addition of an improved cell counting algorithm and a new computer. The computer program that controls the system has been modified to be used with the new computer and to include the new algorithm.

(b) Performance data

(1) Non-clinical tests

The non-clinical tests done for the original Noncon Robo Pachy also apply to the Noncon Robo Pachy F&A, since the device is essentially the same. A new software validation test has been done, to validate the new software. ISO 60601-1 and IS) 60601-1-2 have been repeated because of the new electronics, and a test has been done on the new algorithm.

(2) Clinical tests

A clinical test was performed with four "classifiers", each analyzing the same 40 images of eyes. Each classifier analyzed each image three times. The analyses of the classifiers were analyzed for cell density, hexagonality, and coefficient of variation.

Agreement and variability of the analysis methods was obtained using a sample that included virtually no eyes with Percent Hexagonality <45, Coefficient of Variation >0.41, or Cell Density <2100. Agreement and variability of the analysis methods is not known for eyes with parameters beyond these values.

Agreement Between Methods of Analysis

For a single image from each eye, cell density, coefficient of variation and percent hexagonality were determined by each analysis method. For a given parameter and pair of methods of image analysis, agreement between outputs was assessed. This was done by taking the difference between the two outputs for each image and then calculating the mean difference, and the 95% limits of agreement. These measures of agreement between analysis methods were calculated for each parameter. **Note that each measure estimates the degree of agreement between the different methods of analysis applied to a single image. It does not take into account variation due to repeated image capture. Variations between different images of the same eye will significantly reduce agreement. The listed values should not be taken as estimates of the agreement of the measurements associated with repeated image capture.**

Agreement Between Methods of Analysis for Cell Density			
Analysis Methods	**Mean Difference[1] (%)** - Note: a negative number indicates that first method gives lower results than the second	**Limits of Agreement[2] (%):** ~95% of Differences should fall between these figures	
		Lower 95% Limit of Agreement (Mean Difference - 2*sd)	**Upper 95% Limit of Agreement** (Mean Difference + 2*sd)
Manual vs PC-Assist (with redrawing)	0.06	-0.78	0.9
Manual vs PC-Assist (without redrawing)	0.00	-2.3	2.3
Center vs PC-Assist (with redrawing)	-0.11	-1.47	1.25
Center vs PC-Assist (without redrawing)	-0.17	2.71	2.37
Manual vs Center Method	0.16	-1.1	1.42

Agreement Between Methods of Analysis for Coefficient of Variation			
Analysis Methods	**Mean Difference[1] (%)** - Note: a negative number indicates that first method gives lower results than the second	**Limits of Agreement[2] (%):** ~95% of Differences should fall between these figures	
		Lower 95% Limit of Agreement (Mean Difference - 2*sd)	**Upper 95% Limit of Agreement** (Mean Difference + 2*sd)
Manual vs PC-Assist (with redrawing)	0.43	-2.35	3.21
Manual vs PC-Assist (without redrawing)	0.24	-5.62	6.10
Center vs PC-Assist (with redrawing)	2.38	-4.18	8.94
Center vs PC-Assist (without redrawing)	2.18	-4.18	8.94
Manual vs Center Method	-1.96	--8.58	4.66

Agreement Between Methods of Analysis for Percent Hexagonality			
Analysis Methods	**Mean Difference[1] (%)** - Note: a negative number indicates that first method gives lower results than the second	**Limits of Agreement[2] (%):** ~95% of Differences should fall between these figures	
		Lower 95% Limit of Agreement (Mean Difference - 2*sd)	**Upper 95% Limit of Agreement** (Mean Difference + 2*sd)
Manual vs PC-Assist (with redrawing)	-0.08	-3.32	3.16
Manual vs PC-Assist (without redrawing)	1.47	-3.63	6.57
Center vs PC-Assist (with redrawing)	2.13	-3.03	7.29
Center vs PC-Assist (without redrawing)	3.67	-3.13	10.47
Manual vs Center Method	-2.23	-7.03	2.57

1. Mean Difference is the average across images of:
   100*(Cell Density$_{\text{method 1}}$-Cell Density$_{\text{method 2}}$)
   /(Cell Density$_{\text{method 1}}$+Cell Density$_{\text{method 2}}$)/2]

2. Approximately 2.5% of differences would be expected to fall below the Lower Limit of Agreement and about 2.5% would be expected to fall above the Upper Limit of Agreement. The Limits of Agreement are defined as:
   The Mean Difference (footnote 1, above) ± 2(standard deviation). The standard deviation is calculated across all of the 40 Differences as defined in footnote 1, above.

Variability Associated with the Analysis Methods

The variability of the results associated with each analysis method was assessed. For each of the forty images, cell density, coefficient of variation and percent hexagonality were determined by each method. Each analysis was repeated on the same image three times (presentation was randomized) by each of four "classifiers." For a given analysis method, the standard deviation of the within-image results was calculated as a measure of variability. **Note that this measure estimates the variability associated only with repeated application of the analysis method to a single image. Differences between two or more images of the same eye will significantly increase variability. The listed values should not be taken as estimates of the variability of the measurements associated with repeated image capture.**

Variability Associated with the Analysis Method			
	Standard Deviation (within-image) Expressed as a percentage of the mean value*		
Method of Analysis	Cell Density	Coefficient of Variation	Percent Hexagonality
PC-Assist (with redrawing)	1.14	4.23	3.87
PC-Assist (without redrawing)	0.78	8.02	12.67
Center Method	1.23	6.60	6.42

* Value in table is the mean across 40 images of the variability standard deviation (square root of the sum of the "within-observer" variance plus the "between-observer" variance) divided by the mean value for the image (expressed as a percentage).

(3) Conclusions

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 22 2008

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

Re: K062763
Trade/Device Name: Konan NonCon Robo Pachy F&A
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered Slip Lamp Biomicroscope
Regulatory Class: Class II
Product Code: NQE
Dated: January 23, 2008
Received: January 25, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062736

Device Name: Konan Noncon Robo Pachy F&A

Indications For Use:

The Noncon Robo Pachy F&A is a non-contact ophthalmic microscope, optical pachymeter, and camera intended for examination of corneal endothelium and for measurement of the thickness of the cornea.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

MAB Michaels

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

510(k) Number K062763