

DEC 23 2009

OPKO Instrumentation OTI-Scan 3000
510(k) Summary

K092837

Company: OPKO Instrumentation, LLC.
621 W 20th Street
Hialeah, FL 33010-2432
Phone: 888-268-6756 or 305-575-4178

Contact: Mario Arbesu
Director, Compliance and Regulatory Affairs
OPKO Instrumentation, LLC.
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Miami, FL 33137
Phone 305.575.4631
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Trade Name: OTI-Scan 3000

Device Type: Ultrasonic Pulsed Echo Imaging System

Classification Regulation: 892.1560

Class: II

Panel: Radiology

Product Code: IYO

Predicate Devices: OTI I-Scan (K960622)
OTI Scan with Transducers (K030770)
OTI-Scan HF Module System (K031391)

Device Description: The OTI-Scan 3000 is an Ultrasonic ophthalmic A-Scan and B-Scan system that uses the principles of sonar (pulsed ultrasound) to measure the axial length of the eyes and to visualize the interior of the eye.

Indications for use: The OTI-Scan 3000 ultrasound system is a multi-purpose personal-computer based ultrasonic diagnosis system for ophthalmic applications, intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye, including measurement of the axial length for determination of IOL power.

Performance Data:

Bench-top testing has been performed on the OTI-Scan 3000 including accuracy tests, ultrasonic emissions tests, electrical safety tests and software validation tests.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

Mr. Mario Arbesu
Direction, Compliance and Regulatory Affairs
OPKO Instrumentation, Inc.
4400 Biscayne Blvd.
MIAMI FL 33137

DEC 23 2009

Re: K092837
Trade/Device Name: OTI-Scan 3000
Regulation Number: 21 CFR §892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Codes: IYO and ITX
Dated: August 28, 2009
Received: November 30, 2009

Dear Mr. Arbesu

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the OTI-Scan 3000, as described in your premarket notification:

Transducer Model Number

OTI – Scan 20 MHz HF B-Probe

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 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 market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Mr. Paul Hardy at (301) 796-6542.

Sincerely yours,



for
Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosures

Diagnostic Ultrasound Indications for Use Form

System: OTI-Scan 3000

Intended Use: The OTI-Scan 3000 ultrasound system is a multi-purpose personal-computer based ultrasonic diagnosis system for ophthalmic applications, intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye, including measurement of the axial length for determination of IOL power.

Clinical Application		Mode of Operation						
		B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
General (Track 1 Only)	Specific (Tracks 1 & 3)							
Ophthalmic	Ophthalmic	P						P (A-Mode)
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
Intravascular								
Other (Specify)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
Other (Specify)								
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previous cleared by FDA; E = added under this appendix

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRE, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number

 K092837

Diagnostic Ultrasound Indications for Use Form

System: OTI-Scan 20 MHz HF B-Probe

Intended Use: Transducer for B-Scans with the OTI-Scan 3000 Ultrasound Imaging System.

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic	N						
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
Other (Specify)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
Peripheral Vessel	Other (Specify)							
	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previous cleared by FDA; E = added under this appendix

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 Stock Number K092837