

JUN 29 1998

510(k) Summary

K965223

Submitted By:

EndoSonics Corporation
2870 Kilgore Road
Rancho Cordova, CA 95670
916-638-8008
Contact: Adam Savakus

Summary Preparation:

December 24, 1996

Device:

EndoSonics Resolve Option for the Oracle InVision
Intravascular Imaging System

Common or Usual Name:

Ultrasonic Imaging System

Predicate Devices:

EndoSonics Cathscanner III Intravascular Imaging System
EndoSonics Visions Five 64 3.5F model 84700 Intravascular
Imaging Catheter
EndoSonics Visions Five 64 F/X Model 82700 Intravascular
Imaging Catheter

Millar Mikro-Tip Doppler Catheter Model DC-101
Millar Instruments Incorporated
Houston, TX

Echo-Scan System
Tomtec Imaging System
Boulder, CO

ATL Ultramark 8& 9 Ultrasound Imaging System
Advanced Technology Labs
Bothell WA

CVIS Insight System
Cardiovascular Imaging Systems
A Boston Scientific Company
Sunnyvale, CA

Philips DCI Angiographic Analysis System
Philips Incorporated

510(k) Summary

The EndoSonics Resolve option for the Oracle Imaging system is designed for use in conjunction with imaging catheters for use during diagnostic ultrasound imaging of the peripheral and coronary vasculature to provide an alternative 2D display of ultrasound information. This additional display information is provided in addition to the standard 2D echo image. Information collected during uniform withdrawal of the imaging catheter from the artery is presented in a longitudinal display. The Resolve option also provides a computer assisted boundary detection function which helps identify boundaries within the image, which the operator must explicitly accept or correct before measurements can be performed on these boundaries.

The EndoSonics catheters and imaging system with the Resolve option are substantially equivalent to existing devices such as the EndoSonics Visions Microrail and Visions Model 54700 catheters with the Cathscanner II & III Imaging Systems, the Cook Small Vessel Balloon Angioplasty catheter, the ATL Ultramark 8 imaging system, the Philips DCI Angiographic analysis system, and the CVIS Insight and Ultra Imaging systems and catheters

The acoustic outputs for all models remain unchanged due to the addition of the Resolve software option.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Adam Savakus
Vice President, Clinical and Regulatory Affairs
Endosonics Corporation
2870 Kilgore Road
Rancho Cordova, CA 95670

Re: K965223
Resolve Option for the Oracle InVision Intravascular
Ultrasound Imaging System
Regulatory Class: II
Product Code: 90 IYO
Dated: May 21, 1998
Received: May 22, 1998

Dear Mr. Savakus:

We have reviewed your Section 510(k) 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 catheters intended for use with the Oracle InVision Intravascular Ultrasound Imaging System and the Endosonics Automatic Pull-Back Device (Model PBD-1), as described in your premarket notification:

Catheter Model Number

Visions™ 2.9 F Model 84300	Visions™ F/X 2.9 F Model 82300
Visions™ 3.5 F Model 84700	Visions™ F/X 3.5 F Model 82700

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

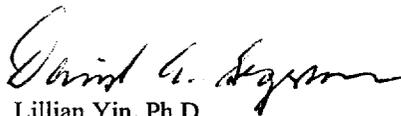
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,



Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

510(k) Number (if known): K965223

Device Name: RESOLVE Option for the ORACLE InVision System

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-operative (Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular										
Laparoscopic										
Musculo-Skeletal										
Other (Specify)		X								

Additional Comments:

Intravascular Imaging; Coronary and Peripheral Vascular - all catheters use the same imaging mold.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Segman
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

Prescription Use (Per 21 CFR 301.109)

510(k) Number K965223