

510(k) Summary

Submitted By: Endosonics Corporation
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Rancho Cordova, CA 95670
916-638-8008
Contact: Adam Savakus

AUG - 6 1997

Summary Preparation: August 20, 1996

Device: Endosonics ColorFlo Option for the Oracle InVision
Intravascular Imaging System

Common or Usual Name: Ultrasonic Imaging System

Predicate Devices: Endosonic 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

Small Vessel Balloon Angioplasty Catheter
Cook Incorporated
Bloomington, IN 47402

ATL Ultramark 8 Ultrasound Imaging System
Advanced Technology Labs
Bothell WA

CVIS Insight System
Cardiovascular Imaging Systems
Sunnyvale, CA

Platinum System with the CVI Option
Philips Imagings Systems

510(k) Summary

The Endosonics ColorFlo 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 blood flow information. This additional flow information is provided as a color overlay over the standard 2D echo image.

The Endosonics Visions catheters and imaging system with the ColorFlo 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 Millar Mikro Tip Doppler catheter, the Philips Platinum Imaging System with the CVI Option, and the CVIS Insight imaging system and catheters.

The Endosonics ColorFlo Option for the Oracle InVision Intravascular Ultrasound Imaging System (the "ColorFlo Option") utilizes a novel patented technology to provide a visual depiction of blood flow through the vessel.

The ColorFlo technology can provide a two dimensional map of relative blood velocity which is overlaid onto the conventional black and white intravascular ultrasound image. Regions which contain faster moving red blood cells are signified by brighter colors, whereas regions of slow motion are less bright. Regions in which there is no or little motion perpendicular to the transducer are presented as clear, or non-colored. These regions appear in grey scale as in the standard display.

The ColorFlo processor detects flow of particles (red blood cells) perpendicular to the imaging plane, or along the long axis of the catheter. This is unlike conventional doppler imaging in which the blood must flow towards or away from the transducer. This is possible by utilizing ultrahigh speed electronics and Endosonics proprietary algorithms.

The ColorFlo system can detect blood velocities in the following range:

The lower limit on particle detection is between 12 cm/sec and 5 cm/sec, depending on the intervening attenuation. (The higher limit is obtained with maximum tissue attenuation between the transducer and region of flow.)

The upper limit on particle detection is between 110 cm/sec and 107 cm/sec, depending on the intervening attenuation. (The lower limit is obtained with maximum tissue attenuation between the transducer and region of flow.)

The ColorFlo Option is available on the Endosonics Oracle InVision Imaging System. This option is an internal option, and no changes to the physical appearance of the system are made with the exception of an additional key on the keyboard.

The acoustic outputs for the 3.5F model 82700 and 84700 catheter when used with the Color Flo option were found to be:

$$\begin{aligned} I_{\text{spta}} &= 5.89 \text{ mW/cm}^2 \\ I_{\text{sppa}} &= 20.77 \text{ W/cm}^2 \end{aligned}$$

The acoustic outputs for the 2.9F model 82300 and model 84300 catheters in color mode operation were found to be:

$$\begin{aligned} I_{\text{spta}} &= 1.13 \text{ mW/cm}^2 \\ I_{\text{sppa}} &= 3.71 \text{ W/cm}^2 \end{aligned}$$



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 1997

Adam Savakus
Vice President
Clinical and Regulatory Affairs
Endosonics Corporation
3078-B Prospect Park Drive
Rancho Cordova, CA 95670

Re: K963290
ColorFlo Option for the Oracle In-Vision
Intravascular Ultrasound Imaging System
Dated: July 2, 1997
Received: July 3, 1997
Regulatory class: II
21 CFR 892.1560/Procode: 90 IYO

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 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.

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 Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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. 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmamain.html>.

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

Enclosure

510(k) Number (if known): K963290

Device Name: **Oracle In-Vision Intravascular Ultrasound Imaging System with ColorFlo Option;
Transducer Model 82700/84700**

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		X						X		
Peripheral Vascular		X						X		
Laparoscopic										
Musculo-Skeletal										
Other (Specify)		X						X		

Additional Comments: _____

This system is indicated for intra-luminal use in both peripheral and coronary applications. There is no difference in operation on acoustic outputs when used for coronary or peripheral vascular imaging.

(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 Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K963290

Prescription Use (Per 21 CFR 801.109)

510(k) Number (if known): K963290

Device Name: **Oracle In-Vision Intravascular Ultrasound Imaging System with ColorFlo Option;
Transducer Model 82300/84300**

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

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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		X						X		
Peripheral Vascular		X						X		
Laparoscopic										
Musculo-Skeletal										
Other (Specify)		X						X		

Additional Comments: _____

This system is indicated for intra-luminal use in both peripheral and coronary applications. There is no difference in operation on acoustic outputs when used for coronary or peripheral vascular imaging.

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