

K 982208

AUG 27 1999

**Submitter**

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**Date summary was prepared: 06.19.98**

**Name(s) of the device**

Proprietary (Trade) Name: IRL VasoScan™ intravascular ultrasound catheter

Common or Usual Name: Diagnostic ultrasound transducer

**Identification of predicate device(s)**

EndoSonics Visions Five-64 3.5F Solid State Intravascular Ultrasound Catheter

EndoSonics Corporation  
3078 B Prospect Park Drive  
Rancho Cordova, CA 95670

## **Description of the device**

The outer body of the IRL VasoScan™ intravascular ultrasound catheter is manufactured from Vestamid 12. The transducer consists of a 64-element array, supported on a polyimide film. The IRL VasoScan™ intravascular ultrasound catheter has a usable length of 1350mm and is designed to provide high quality intra-arterial ultrasound images of the coronary arteries. The IRL VasoScan™ intravascular ultrasound catheter is designed to be combined with conventional coronary angiography for the purposes of diagnosis, assistance with the choice of therapeutic modalities and assessment of the immediate outcome of such treatment.

Qualification testing covering biocompatibility, mechanical strength, electrical safety and imaging has been performed and has proved that, when used according to the instructions provided, the IRL VasoScan™ intravascular ultrasound catheter will operate as intended. Every IRL VasoScan™ intravascular ultrasound catheter is final tested to ensure conformance to product specification prior to sterilization and subsequent shipment.

## **Intended Use**

The indications for use of the IRL VasoScan™ intravascular ultrasound catheter are for the visualization of the lumen and structure of the coronary arteries in patients affected by atherosclerosis who are suitable candidates for percutaneous transluminal coronary angioplasty (PTCA).

When using the catheter, the following procedure is followed:

The catheter is carefully removed from the package. The outer surface is washed with sterile water and the circular proximal catheter connector is attached to the catheter interface module. The catheter is introduced into the coronary artery using the vascular entry technique of choice through a guide catheter with an internal diameter of at least 0.074in using a 0.014in guide wire. The catheter is then advanced to the area of interest and the intravascular coronary ultrasound imaging carried out.

### **Comparison of device characteristics to predicate**

A comparison was made between the physical and performance characteristics of the IRL VasoScan™ intravascular ultrasound catheter and the physical and performance characteristics of a legally marketed predicate product. This analysis revealed that the IRL VasoScan™ intravascular ultrasound catheters are substantially equivalent to that predicate product.

### **Non clinical testing**

Biocompatibility tests were carried out on the IRL VasoScan™ intravascular ultrasound catheter, including cytotoxicity, hemolysis and coagulation. Validation of the sterilization cycle used was also undertaken. All testing was supportive of the claims (i.e. indications for use).

### **Conclusion**

In conclusion, the basis for substantial equivalence between the IRL VasoScan™ intravascular ultrasound catheter and the legally marketed predicate product is that the products are predominately similar and that the difference between the products does not raise new issues of safety and effectiveness.

Based upon the information provided herein, it is our conclusion that the IRL VasoScan™ intravascular ultrasound catheter is substantially equivalent to the EndonSonics Visions Five 64 3.5F Solid State Intravascular Ultrasound Catheter.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Intravascular Research Limited  
c/o Louise C. Myers  
14808 N.E. 66<sup>th</sup> Street  
Redmond, WA 98052Re: K982208  
IRL VasoScan™ Intravascular  
Ultrasound Catheter  
Regulatory Class: II  
Product Code: ITX  
Dated: June 1, 1999  
Received: June 4, 1999

Dear Ms. Myers:

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 transducer intended for use with the Vasoscan™ Intravascular Ultrasound Catheter as described in your premarket notification:

Transducer Model Number  
2.9 Fr, 30 MHz

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

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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.

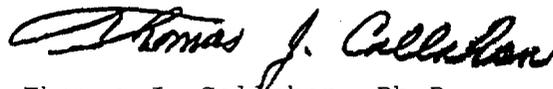
This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, 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

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>".

Sincerely yours,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular,  
Respiratory and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INDICATIONS FOR USE

### 510(k) Number

K982208.

### Device Name

IRL VasoScan™ intravascular ultrasound imaging system.

### Indications for Use

The indications for use of the IRL VasoScan™ intravascular ultrasound imaging system are for the visualization of the lumen and structure of the coronary arteries in patients affected by atherosclerosis who are suitable candidates for percutaneous transluminal coronary angioplasty (PTCA). The IRL VasoScan™ intravascular ultrasound catheter is for use only with the IRL VasoScan™ intravascular ultrasound imaging system.

### Contraindications

Whenever possible, the clinician should eliminate or minimize factors that increase risk. These include hypokalemia or other reversible causes of ventricular irritability, digitalis toxicity, febrile illness, decompensated heart failure, severe hypertension and significant anaemia.

The device is not indicated for use in the cerebral arteries or for uses other than those indicated above.

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### Concurrence of CDRH, Office of Device Evaluation (ODE)

- Prescription Use (per 21 CFR 801.109)
- Over the Counter Use

  
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(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number K982208