

JAN 14 1999

EndoSonics Corporation
Visions 8.2F PV Models 88900

510(k) Premarket Notification
June 30, 1998

510(k) Summary

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

Summary Preparation: June 30, 1998

Device: EndoSonics Visions 8.2F PV Intravascular Imaging Catheter

Common or Usual Name: Ultrasonic Imaging Catheter

Predicate Devices: EndoSonics Visions 3.5F model 84700 Intravascular Imaging Catheter
EndoSonics Cathscanner Model 302 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

510(k) Summary

The EndoSonics Visions 8.2F PV catheter is a diagnostic device intended for use in diagnostic ultrasound imaging of the peripheral vasculature.

The Visions 8.2F PV is available in an over-the-wire design. The catheter has a 7.0F shaft with a maximum distal diameter of 8.2F.

The EndoSonics Visions 8.2F PV catheter is substantially equivalent to existing devices such as the EndoSonics Cathscanner Model 302 and Visions Model 84700 catheters with the Oracle (Cathscanner III) Imaging System, the Cook Small Vessel Balloon Angioplasty catheter, the ATL Ultramark 8 imaging system, the Millar Mikro Tip Doppler catheter, and the CVIS Insight imaging system and catheters

All catheters are manufactured from similar biocompatible materials. Biocompatibility testing has been performed.

Testing of the EndoSonics Visions catheters include radiopacity, tensile strength of the catheter shaft, catheter distal end tensile strength, profile measurements, and biocompatibility. These tests demonstrated the devices meet or exceed specification as well as catheter tip profiles were within specification tolerances. Tensile strength of the catheter shaft and catheter tip show that the catheter tip met design specifications.

The acoustic outputs for the Visions 8.2F PV catheter were found to be:

$$\begin{aligned} I_{spta} &= 0.0158 \text{ mW/cm}^2 \\ I_{sppa} &= 0.044 \text{ W/cm}^2 \\ MI &= 0.012 \end{aligned}$$



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 14 1999

Mr. Adam Savakus
Vice President, Clinical and Regulatory Affairs
EndoSonics Corporation
2870 Kigore Road
Rancho Cordova, CA 95670

Re: K982329
Trade Name: Visions 8.2F PV Ultrasonic Imaging Catheter
(Model 88900)
Regulatory Class: II
Product Code: ITX
Dated: October 16, 1998
Received: October 19, 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market 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 requirements, 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) 594-4586. 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" (21CFR 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/dsma/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

510(k) Number: K98 2329

Device Name: Visions 8.2F PV Ultrasoinic Imaing Catheter (Model 88900)

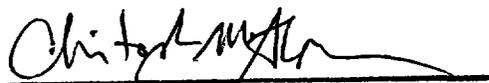
Indications for Use:

The Visions catheters are designed for use in the evaluation of vascular morphology in blood vessels of the peripheral vasculature by providing a cross-sectional image of such vessels.

The Visions ultrasound imaging catheter is designed for use as an adjunct to conventional angiographic procedures to provide:

- (1) An image of the vessel lumen and wall structures.
- (2) Dimensional measurements from the image.

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K982329

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)