

AUG 30 1999

EndoSonics Corporation  
Trak Back Device

K990271  
510(k) Premarket Notification  
January 26, 1999

## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

### ENDOSONICS Trak Back Device

As an accessory, the Trak Back Device does not affect the safe and effective use of the EndoSonics Intravascular Ultrasonic Imaging System or the Endosonics Imaging catheters.

#### DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The Trak Back device is substantially equivalent in intended use and technologic characteristics to cardiovascular accessory devices: the EndoSonics Automatic Pull Back Device, the CVIS Catheter Pull-Back Device and the Intertherapy Interpret Catheter Linear Translator. These predicate devices are legally commercially available.

#### COMPANY AND CONTACT PERSON

EndoSonics Corporation  
2870 Kilgore Road  
Rancho Cordova, CA 95670

Adam Savakus  
Vice President, Clinical and Regulatory Affairs  
916-638-8008

#### DEVICE NAME

Trak Back

#### PREDICATE DEVICE(S)

1. EndoSonics Automatic Pull Back Device
2. CVIS Catheter Pull-Back Device
3. Intertherapy Interpret Catheter Linear Translator

## DESCRIPTION OF DEVICE

The Trak Back is a battery powered device that is used in the catheterization laboratory during intravascular ultrasound assessment. The Trak Back has a nominal linear travel distance which is only limited by the catheter length, and provides a uniform, slow pull back rate of the catheter's imaging element. The speed is selectable between 1 mm/sec or 0.5mm/sec. The Trak Back has no direct patient contact. The device is constructed of materials common to the medical industry for both patient and non-patient contact devices and equipment.

## STATEMENT OF INTENDED USE OF THE DEVICE

The EndoSonics Trak Back is intended for use as a pull back accessory to the EndoSonics Intravascular Ultrasound Imaging Catheters. The Trak Back Device withdraws the imaging catheter from the vessel through the guide catheter.

## INTENDED USE OF PREDICATE DEVICE

1. The EndoSonics Automatic PBD is intended for use as a pull back accessory to the EndoSonics Intravascular Ultrasound Imaging Catheters. The Automatic PBD withdraws the imaging catheter from the vessel through the guide catheter.
2. The Auto PBD is intended to be used as a pull-back accessory to CVIS intravascular ultrasound catheters. The Auto PBD pulls back the imaging element inside the catheter while the outer catheter body is stationary in the vessel.
3. The CVIS Catheter Pull-Back Device is intended to be used for uniform, slow velocity pull-back of intravascular ultrasound catheters.
4. The Intertherapy Interpret Catheter Linear Translator is intended to be used for uniform, slow velocity pull-back of intravascular ultrasound catheters.

## COMPARISON OF TECHNOLOGICAL CHARACTERISTICS BETWEEN DEVICE AND PREDICATE DEVICE

The Trak Back and the predicate devices have substantially equivalent technological characteristics (materials, design, specifications, and mode of operation). These accessory devices have no patient contact. The devices are designed so catheters will attach to a movable carriage. The Trak Back incorporates pull-back rates comparable to predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 30 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Richard Hebert  
Vice President, Quality Assurance,  
Clinical and Regulatory Affairs  
Endosonics  
2870 Kilgore Road  
Rancho Cordova, CA 95670

Re: K990271  
Endosonics Trak Back Device  
Regulatory Class: II (Two)  
Product Code: DQX  
Dated: June 4, 1999  
Received: June 8, 1999

Dear Mr. Hebert:

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.

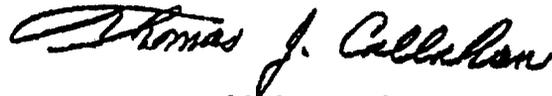
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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.

Page 2 - Mr. Richard Hebert

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) 594-4648. 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 (if known): K990271

Device Name: Endosonics Trak Back Disposable Pullback Device

Indications For Use: The Trak Back can be used with the Visions Five-64 series ultrasound imaging catheter. The Trak Back withdraws the imaging catheter from the vessel through the guide catheter.

(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 Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K990271

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)