III. **510(k) SUMMARY**
(As required by 21 C.F.R. 807.92)

AUG 29 2012

A. Submitter Information

Submitter's Name:	Thomas Medical Products, Inc.
Address:	65 Great Valley Parkway Malvern, PA 19355
Telephone Number:	(610) 296-3000
Facsimile:	(610) 296-4591
Contact Person:	Peter J. Rapp
Title:	Director, Quality Assurance/Regulatory Affairs
Date Submission Prepared:	November 30, 2000

B. Device Information

Trade name:	SafeSheath MSP™ Introducer Kit with Integral Hemostasis Valve
Classification Names:	Catheter Introducer
Predicate Devices:	Tearaway Sheath Introducer Set with Integral Hemostatis Valve (K934901)
Device Description:	The components of the SafeSheath MSP™ Introducer Kit consists of a sheath with sideport tubing, stopcock and heomostasis valve. The distal end of the sheath may be configured for a straight sheath or with a curve. The sheath length must be able to provide a conduit from the insertion site to the epicardial target sites. A guiding dilator will accompany the straight or curved sheath, to assist with the guiding and steering of the sheath to the intended location. A standard vessel dilator that will assist in insertion. A .035" x 135 cm guidewire. A standard 12cc syringe. A 18 gauge XTW introducer needle. A transvalvular insertion tube, which can be used to open the hemostasis valve during insertion of delicate leads or catheters, may also be packaged with the introducer kit. A Pacing Lead Stabilizer (PLS) that can be used to facilitate the removal of the introducer sheath, may also be packaged with the introducer kit.
Intended Use:	The SafeSheath MSP™ Introducer Sheath Kit with Integral Hemostasis Valve is for introduction of pacing leads or catheters during pacing lead or defibrillatory catheter placement procedures.

C. Comparison of Required Technological Characteristics

All technological characteristics of the SafeSheath MSP™ Introducer Sheath Kit with Integral Hemostasis Valve are substantially equivalent to the predicate device (K934901) including product design, packaging, sterilization, and labeling.

D. Substantial Equivalence

Thomas Medical Products considers the SafeSheath MSP™ Introducer Sheath Kit with Integral Hemostasis Valve to be substantially equivalent to the following legally marketed predicate devices: Tearaway Sheath Introducer Set with Integral Hemostasis Valve (K934901).

E. Qualification Testing

Thomas Medical Products qualification testing of the SafeSheath MSP™ Introducer Sheath Kit with Integral Hemostasis included dimensional, visual, leak testing, Valve Body to Sidearm pull test, PVC tubing to Stopcock pull test and PVC Tubing to Valve Housing Peel test. All samples passed the protocol qualification testing requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 29 2012

Oscor Inc.
c/o Ms. Mila Doskocil
Vice President of Regulatory Affairs and Quality Assurance
3816 DeSoto Boulevard
Palm Harbor, FL 34683

Re: K122084
Trade/Device Name: Introducer Set, Model Adelante-S Series
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II (two)
Product Code: DYB
Dated: August 15, 2012
Received: August 17, 2012

Dear Ms. Doskocil:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510k Number (if known) –

Device Name: **Introducer Sets, Adelante®-S Series**

The introducer sets, Adelante®-S Series are intended for introduction of pacing leads or catheters into the body.

Prescription Use _X_ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

(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 Devices

510(k) Number K122084