K012922

SEP 2 5 2001

510(k) Summary
(As required by 21 CFR 807.92)

A. Submitter Information

Submitter's Name:	St. Jude Medical, Daig Division
Address:	14901 DeVeau Place Minnetonka, Minnesota 55345-2126 U.S.A.
Telephone Number:	952-933-4465
Contact Person:	Kirk Honour
Date Submission Prepared:	August 24, 2001

B. Device Information

Common or Usual Name:	Ultraflex™ EV Hemostasis Introducer
Classification Name:	Catheter Introducer
Predicate Device:	Ultaflex™ Hemostasis Introducer St. Jude Medical, Daig Division
Device Description:	The Ultraflex™ EV (9-12F) Hemostasis Introducers are introducers designed to provide easy access to the vascular system while providing convenient temporary closure of a standard indwelling introducer access site. The introducers include a sheath, hub, hemostasis valve, sideport for 3-way stopcock, and dilator. The introducers are provided sterile, and are intended for single-use only.
Intended Use:	The Ultraflex™ EV Hemostasis Introducers are designed for the introduction of angiographic catheters, closed end catheters, balloon catheters and electrodes into a vessel where minimizing blood loss is essential.

C. Comparison of Required Technological Characteristics

All technological characteristics of the Ultraflex™ EV Hemostasis Introducers are substantially equivalent to the predicate device including product design, packaging, sterilization, and labeling.

D. Support of the Substantial Equivalence

St. Jude Medical, Daig Division considers the Ultraflex™ EV Hemostasis Introducers to be substantially equivalent to the predicate device, Ultraflex™ Hemostasis Introducers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 5 2001

Mr. Kirk Honour
Regulatory Affairs
St. Jude Medical
Daig Division
14901 Deveau Place
Minnetonka, MN 55345

Re: K012922
Trade Name: Ultraflex™ EV Hemostasis Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer.
Regulatory Class: II
Product Code: DYB
Dated: August 31, 2001
Received: August 31, 2001

Dear Mr. Honour:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Ultraflex™ EV Hemostasis Introducer

Indications for Use:

The Ultraflex™ EV Hemostasis Introducer is designed for the introduction of angiographic catheters, closed end catheters, balloon catheters and electrodes into a vessel where minimizing blood loss is essential.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012922

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)