

K973840

MAY 21 1998

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

A. Submitter Information

Submitter's Name: Daig Corporation, a Division of St. Jude Medical, Inc.

Address: 14901 Deveau Place
Minnetonka, MN
55345-2126

Telephone Number: (612) 933-4700

Contact Person: Dean Bruhn-Ding

Submission Prepared: October 6 , 1997

B. Device Information

Common or Usual Name: Intra-Cardiac Introducer
Catheter Introducer

Classification Name: Catheter Introducer

Predicate Device: Fast-Cath™ Transseptal Catheter Introducer

Device Description: The Daig Intra-Cardiac Introducer includes a radiopaque sheath and dilator with specially curved distal portions to accommodate specific requirements. The introducer sheath is fitted with a hemostasis valve to minimize blood loss during catheter introduction / exchange. A side port with a three way stop cock is provided for air aspiration, fluid infusion, blood sampling, etc.

Intended Use:

The Fast-Cath™ Intra-Cardiac Introducer is intended for use when introducing various cardiovascular catheters or biopsy devices into the heart

C. Comparison of Required Technological Characteristics

All technological characteristics of the Fast-Cath™ Intra-Cardiac Introducer with new indication for use are identical to the predicate device including product design, packaging, sterilization, and labeling (with the exception of the new indications).

D. Support of Substantial Equivalence

The Daig Corporation has received clearance to market the Fast-Cath™ Introducer for use in introducing cardiovascular catheters into the heart through the interatrial septum. The new indication for use included within the scope of this 510(k) also encompasses the use of Fast-Cath™ Introducers for Intra-Cardiac procedures that do not require penetration of the interatrial septum.

The clinical literature has demonstrated that the use of an introducer to perform endomyocardial biopsy may reduce the complications associated with this procedure. Similar commercially available catheter introducers have been successfully used for introducing various cardiovascular catheters and biopsy devices into the heart. At least one of these devices bears labeling that is substantially equivalent to the indication for use included within the scope of this 510(k).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 1998

Mr. Dean Bruhn-Ding, RAC
Director of Regulatory Affairs
DAIG Corporation
14901 Deveau Place
Minnetonka, MN 55345-2126

Re: K973840
Trade Name: Fast-Cath™ Intra-Cardiac Introducer
Regulatory Class: II
Product Code: DYB
Dated: February 19, 1998
Received: February 20, 1998

Dear Mr. Bruhn-Ding:

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 (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 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) 594-4618. 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): K973840

Device Name: Fast-Cath™ Intra-Cardiac Introducer

Indications for Use:

The Fast-Cath™ Intra-Cardiac Introducer is indicated for use when introducing various cardiovascular catheters or biopsy devices into the heart.

DMAR

(Division Sign-Off)
Division of Cardiology
and Neurological
510(k) Number K973840

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

~~_____~~
Over-The-Counter Use : _____
(Optional Format 1-2-96)