SEP 16 1998

510(k) Summary

(as required by 21 CFR 807.92)

A. Submitter Information

Submitter's Name	Daig Corporation, a St. Jude Medical Company
Address	14901 DeVeau Place Minnetonka, Minnesota 55345-2126 U.S.A.
Telephone Number	(612) 933-4700
Contact Person	Dean Bruhn-Ding
Submission Prepared	June 19, 1998

B. Device Information

Common or Usual Name	Intra-Cardiac Introducer, Catheter Introducer
Classification Name	Catheter Introducer
Predicate Device	Fast-Cath™ Intra-Cardiac 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 sideport with a Three-way stopcock 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 contraindications and instructions for use).

D. Support of the Substantial Equivalence

The clinical literature has demonstrated that the use of an introducer to perform endomyocardial biopsy and cardiac catheterization may reduce the complications associated with this procedure. Literature supports the use of these products from both venous and arterial access sites. Similar commercially available catheter introducers have been successfully used for introducing various cardiovascular catheters and biopsy devices into the heart from both the arterial and venous access sites. In addition, Daig's Fast-Cath™ Transseptal Catheter Introducers (Reference Device) are routinely used on the septal side of the heart via transseptal access.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 1998

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

Re: K982187
Trade Name: Fast-Cath™ Intra-Cardiac Introducer
Regulatory Class: II
Product Code: DYB
Dated: June 19, 1998
Received: June 22, 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) 594-4586. 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 (if known): K982187

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.

(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 K982187