

OCT 19 1998

510(k) Summary

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**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	Michael G. Schultz
Submission Prepared	June 30, 1998

**B. Device Information**

Common or Usual Name	Spyglass™ 5Fr Angiographic Catheter
Classification Name	Angiographic Catheter
Predicate Device	Spyglass™ Angiographic Catheter Family (K944284, K962805, and K965249)
Device Description	Daig Spyglass™ angiographic catheters are radiopaque polymer reinforced with braided stainless steel. This construction yields a small diameter catheter, which retains strength and high flow rate capabilities. A soft atraumatic tip provides good memory and protects against vessel damage. Preformed tip shapes matching or complementing specific anatomy allow access into a variety of vessels.
Intended Use	The Daig Spyglass™ angiographic catheters are designed for delivery of radiopaque contrast media during angiographic procedures.

**C. Comparison of Required Technological Characteristics**

All technological characteristics of the Spyglass™ 5Fr Angiographic Catheter are identical to the predicate device (K962805) including product design, packaging, sterilization, and labeling.

**D. Support of the Substantial Equivalence**

Daig Corporation considers the Spyglass™ 5Fr Angiographic Catheter to be substantially equivalent to the following predicate devices: Spyglass™ Angiographic Catheter (formerly called Control™ Angiographic Catheter) received marketing clearance on March 3, 1995 (K944284) and Spyglass™ Angiographic Catheter received marketing clearance on October 28, 1996 (K962805).



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 19 1998

Mr. Michael G. Schultz  
Quality Systems Manager  
DAIG Corporation  
14901 Deveau Pl.  
Minnetonka, MN 5345-2126

Re: K982299  
Trade Name: 5FR Spyglass™ Angiographic Catheter  
Regulatory Class: II  
Product Code: DQO  
Dated: September 25, 1998  
Received: September 28, 1998

Dear Mr. Schultz:

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.

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): K98 2299

Device Name: 5Fr Spyglass™ Angiographic Catheter

Indications for Use:

The 5Fr Spyglass™ Angiographic Catheter is designed for delivery of radiopaque contrast media during angiographic procedures.

(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 K982299

Prescription Use   
(Per 21 CFR 801.109)

OR

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