

JUL 15 1999



K983940

## Adam Spence Corporation

1746 Route 34, P.O. Box 1467, Wall, NJ 07719, (732) 681-7070, Fax, (732) 681-1503

### 510(k) SUMMARY

Trade Name: Adam Spence Corp. Percutaneous Catheter Introducer

Common or usual Name: Catheter Sheath Introducer System

Classification Name: Catheter, Introducer, Class II device (per 21 CFR 870.1340)

Equivalent Device: Daig Corporation Fast-Cath™ Transseptal Catheter Introducer, K964518

Contact Name: Carol Rosenbloom

Description and Intended Use: The Adam Spence Corp. Percutaneous Catheter Introducer (PCI) is a disposable device intended for use in diagnostic angiographic procedures. The Adam Spence Percutaneous Catheter Introducer is intended to provide a means for percutaneous vascular access while minimizing the back flow of blood during the introduction of cardiovascular devices such as catheters and guide wires.

Performance Standards:

- Performance standards have not been established under Section 514 of the Food, Drug and Cosmetic Act.
- **ANSI MD70.1-1983**, American National Standard for Medical Material – Luer Taper Fittings – Dimensional Requirements for Luer Lock Fittings
- **ISO/DIS 11070.2**: Sterile, Single-Use Intravascular Catheter Introducers, Sections 4, 7, 9, and 10.

Biocompatibility: All appropriate biocompatibility tests have been performed per ISO 10993, Biological Evaluation of Medical Devices (Per General Program Memorandum #G95-1)

Summary of Substantial Equivalence: The Adam Spence Percutaneous Catheter Introducer has the same intended use as other catheter sheath introducers on the market (ie., Daig Fast-Cath™ Hemostasis Introducer.) Additionally, based on the technological characteristics and performance testing the Adam Spence Percutaneous Catheter Introducer is substantially equivalent in its basic design, construction, material, safety, efficacy and intended use to currently marketed catheter sheath introducer systems.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS		
FEATURE	ADAM SPENCE PCI	PREDICATE DEVICE
Manufacturer	Adam Spence Corporation	Daig Corporation
Sterile Packaging	Sterile and Bulk Packaged	Sterile Pack
Sterilization Method	Ethylene Oxide Gas	Ethylene Oxide Gas
Shelf Life	3 Years	3 Years
Available Sizes	4 through 9 French size	4 through 9 French size
Tensile properties	Exceeds Requirement	Exceeds Requirement
Valve/Sheath Leak	No Leakage	4 Fr. leaked after dilation
Insertion/Withdrawal	Substantially Equivalent to Predicate	Acceptable
Air Aspiration	Greatly Exceeded Predicate Device	Acceptable
Tip Peelback	No Damage or Peelback: Lower average insertion force required to puncture skin than predicate device.	No Damage or Peelback: Higher average insertion force required to puncture skin than ASC PCI.

Prepared By: Carole A. Luranku Date: 4/20/99



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 15 1999

Ms. Carol Rosenbloom  
Adam Spence Corporation  
1746 Route 34  
P.O. Box 1467  
Wall, NJ 07719

Re: K983940  
EZ-Intro™ Percutaneous Catheter Introducer  
Regulatory Class: II (two)  
Product Code: 74 DYB  
Dated: April 16, 1999  
Received: April 21, 1999

Dear Ms. Rosenbloom:

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.

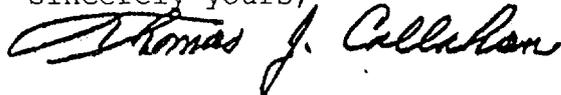
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Ms. Carol Rosenbloom

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) 594-4648. 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" (21 CFR 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): K983940

Device Name: \_\_\_\_\_

Indications For Use:

**STATEMENT OF INDICATIONS FOR USE**

The Adam Spence Percutaneous Catheter Introducer is intended to provide a means for percutaneous vascular access while minimizing the back flow of blood during the introduction of cardiovascular devices such as catheters and guide wires.

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

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

*[Handwritten Signature]*  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number \_\_\_\_\_

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_