K040498

JUL 0 2 2004

C. 510(k) Summary

Applicant	Sedat, Inc. 76 Bedford Street, #33 Lexington, MA 02420 Contact: Jean-Pierre Desseignes Telephone: 781/674-2050 Facsimile: 781/674-3115 Email: j-p.desseignes@sedat.com
Manufacturer	Sedat France Address Contact
Date	February 24, 2004
Device Name	MYSHELL
Common Name	Y-Connector/Hemostatic Valve (per 21 CFR 870.4290)
Summary of Substantial Equivalence	MYSHELL is substantially equivalent in respect to the intended use, design and method of operation of the Copilot™ Bleedback Control Valve manufactured by Guidant Corporation (K991102).
Device Description	MYSHELL is an ergonomically designed y-connector/hemostatic valve that accepts materials up to 9F in size (<.098"). The watertight double hemostatic silicone valve is manipulated by a valve opening mechanism on the external body of MYSHELL. The opening mechanism allows for precise control of the internal valve: press gradually on the mechanism for a controlled opening, push the mechanism entirely in for a complete and locked opening, or completely close the valve by depressing on the mechanism in its locked position.
Intended Use	MYSHELL is indicated for maintaining a seal around diagnostic/interventional devices with an outside diameter <9F (<.098") during interventional procedures. The 3-way stopcock, Alligatork and guidewire introducer are accessories used in conjunction with MYSHELL to facilitate interventional procedures.
Indications Statement	MYSHELL is indicated for maintaining a seal around diagnostic/interventional devices with an outside diameter <9F (.098") during interventional procedures.
Technological Characteristics	- Ergonomic design fits entirely and comfortable into the hand. - MYSHELL accepts catheters up to 9F in size. - Internal double hemostatic silicone valve is watertight. - Transparency ensures total visibility - The valve opening mechanism allows for gradual or complete opening/closing.
Performance Data	The safety and efficacy of MYSHELL and its accessories, the 3-way stopcock, guidewire introducer and Alligatork, have been demonstrated through a variety of preclinical tests and analyses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 0 2 2004

Sedat, Inc.
c/o Mr. Peter C. Wood
Regulatory Affairs Counsel
4 Harvard Place, #1
Charlestown, MA 01960

Re: K040498
MYSHELL
Regulation Number: 21 CFR 870.4290
Regulation Name: Cardiopulmonary Bypass Adaptor, Stopcock, Manifold, or Fitting
Regulatory Class: Class II (two)
Product Code: DTL
Dated: June 16, 2004
Received: June 17, 2004

Dear Mr. Wood:

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), please contact the Office of Compliance at (301) 594-4646. 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) you may obtain. 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K040498

B. Indications for Use

510(k) Number (if known):

K040498

Device Name:

MYSHELL

Indications for Use:

MYSHELL and its accessories are indicated for assisting, manipulating and maintaining a seal around diagnostic/interventional devices with an outside diameter <9F (.098") used in interventional procedures.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lechner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040498