DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 2005

Sedat
c/o Excaelia™
Ms. Laetitia Bernard
President
45900 Parsippany Court
Temecula, CA 92592

Re: K042449
Dolphin Inflation Device
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic injector and syringe
Regulatory Class: II (two)
Product Code: MAV
Dated: March 10,2005
Received: March 14,2005

Dear Ms. Bernard:

This letter corrects our substantially equivalent letter of April 18, 2005 regarding the address change.

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 (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 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 continue 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 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (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

Indications for Use

510(k) Number (if known): K042449

Device Name:
DOLPHIN INFLATION DEVICE

Indications for Use:
DOLPHIN Inflation Device is intended for use during cardiovascular procedures to create, maintain and monitor pressure in the balloon catheter.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFK 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. Richmond

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K042449

K042449

APR 19 2005

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 135, Route Neuve 69540 Irigny FRANCE	Contact: Jean-Pierre Desseignes Telephone: 33(0) 4 72 39 74 14 Facsimile: 33(0) 4 78 51 89 67 Email: j-p.desseignes@sedat.com
Date	August 26, 2004	
Device Name	DOLPHIN Inflation Device	
Common Name	Angiographic injector/syringe	
Summary of Substantial Equivalence	DOLPHIN is substantially equivalent, with respect to the intended use, conditions of use, and design, of the currently marketed Indeflator 20/30 (K961471, Product Code: MAX, Regulation: 870.1650). The DOLPHIN is substantial equivalent, with respect to materials, packaging process and location, as well as sterilization and location, to the Myshell (K040498, Product Code: DTL, Regulation: 870.4290).	
Device Description	DOLPHIN is a single-use, sterile, and ergonomically designed inflation device used in cardiovascular procedures to pressurize (inflate) and depressurize (deflate) balloon catheters. The device itself consists of two components – the inflation device and large volume syringe (30 cc). The manually operation of the DOLPHIN is achieved by the manipulation of a large handle to drive a piston housed within the body of the device. Careful and controlled inflation is achieved by rotating the handle clockwise. During inflation a unique cam locking mechanism maintains pressure even if the user lets go of the device. Instantaneous deflation, regardless of balloon size, is made possible by the release of the dual locks located on device as well as a large, 30 cc syringe that is sold with each Dolphin Inflation Device. All the while during inflation or deflation pressure is displayed and can be monitored on a large analog gauge mounted on top of the device.	
Intended Use	DOLPHIN Inflation Device is intended for use during cardiovascular procedures to create, maintain and monitor pressure in the balloon catheter.	
Technological Characteristics	▪ Ergonomic design of the DOLPHIN permits easy holding (grained side panels) and handling (slip-free buttons). ▪ A unique cam locking mechanism maintains high pressure (up to 30 ATM) and allows for a fast and easy release of pressure. ▪ The 30 cc syringe allows rapid deflation, regardless of balloon size. ▪ Very stable on the operating drape with an easy to read pressure gauge. ▪ Suitable for right and left-handed personnel. ▪ Precise pressure increase with a simple wrist movement. ▪ Clear materials facilitate the detection of air bubbles and debubbling.	
Performance Data	The safety and efficacy of DOLPHIN has been demonstrated through a variety of preclinical tests and analyses, as well as non-clinical comparisons to the Indeflator 20/30.	