K082155 Pg. 1 of 2

VII. 510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular §807.92, the following summary of information is provided:

DEC 15 2008

A. Submitted by

Catherine Charles
Director of Regulatory Affairs and Quality Assurance
Sedat
135, Route Neuve
69540 Irigny -France
Telephone: +33 472 397 414
Fax: +33 478 518 967

B. Device Name

Trade or Proprietary Name:	*Sedat Flamingo*
Common or Usual Name:	Angiographic injector/syringe
Classification Name:	Ballon Inflation Syringe
Device Class:	Class II
Classification:	870.1650
Product Code:	MAV

C. Predicate Devices

The subject device is substantially equivalent to Sedat's Dolphin Device (K042449).

D. Device Description

The *Sedat Flamingo* inflation device 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 FLAMINGO is achieved by the manipulation of a grip 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 button locks located on device.

E. Intended Use

The Sedat *Flamingo* is indicated for use during cardiovascular procedures to create, maintain and monitor pressure in the balloon catheter.

F. Substantial Equivalence

Data were provided which demonstrated the *Sedat Flamingo* inflation device is to be substantially equivalent to Sedat's Dolphin Device (K042449). The substantial equivalence is based upon equivalence in indications for use, design, material, and function.

G. Summary of Non-Clinical Tests

Mechanical testing was presented.

H. Summary of Clinical Tests

(Not Applicable).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2008

SEDAT
c/o Mr. Charles Cousin
President, Excaelia
8895 Towne Centre Drive #105-416
San Diego, CA 92122

Re: K082755
Trade/Device Name: Sedat Flamingo
Common Name: Syringe, Balloon Inflation
Regulation Number: 21 CFR 870.1650
Regulatory Class: II
Product Code: MAV
Dated: November 24, 2008
Received: November 25, 2008

Dear Mr. Cousin:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K082755

Device Name: *SEDAT Flamingo*

Indications for Use:

The Sedat *Flamingo* is indicated 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 CFR 807 Subpart C)

(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 Devices
510(k) Number K082755