K990396

IV. 510(k) Summary

A. *Submitter / 510(k) Sponsor*

John W. Smith, Manager of Regulatory Affairs

Baxter Research Medical, Inc.
6864 South 300 West
Midvale, Utah 84047
USA

Phone (801) 565-6213

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Date prepared: 1999-02-05

B. *Device Name*

T-AnastaFlo, IVS-T-xxxx

Classified by FDA under 21 CFR § 870.4210, *Cardiopulmonary bypass vascular catheter, cannula, or tubing.*

C. *Predicate Device*

Name:	Rivetti-Levinson Intraluminal Shunt
Manufacturer:	Heyer-Schulte Neurocare
510(k) Number:	K972261
SE Decision Date:	1997-09-15

D. *Device Description*

The T-AnastaFlo is a sterile, single use, disposable shunt composed of two silicone bulbs on the distal ends of a flexible silicone tubular shaft. Another silicone tubular shaft is attached perpendicular to the middle of the shunt, ending with a perfusion port stopcock.

Each T-AnastaFlo is individually packaged sterile and non-pyrogenic in a sealed, peel-type pouch.

E. *Intended Use*

The T-AnastaFlo is indicated for use in preventing ischemia by the shunting and/or perfusion of blood or cardioplegic solution distal to the anastomosis site during the construction of coronary artery bypass grafts.

F. *Summary of Comparison, Proposed and Predicate Devices*

The proposed device is substantially equivalent to the cited predicate device in intended use, technology, materials, and design.

This conclusion is based upon tests performed for device flow rate, leak characteristics, and tensile strength, and upon the equivalence of materials, design and intended use for the proposed and predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 1999

Mr. John W. Smith
Manager of Regulatory Affairs
Baxter Healthcare Corporation
Research Medical, Inc.
6864 South 300 West
Midvale, UT 84047-1051

Re: K990396
T-AnastoFlo
Regulatory Class: II (Two)
Product Code: 74 DWF
Dated: July 9, 1999
Received: July 12, 1999

Dear Mr. Smith:

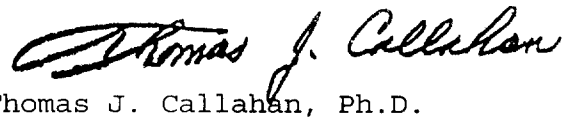
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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.

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" (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

D. Indications for Use Statement

510(k) Number (if known): K990396

Device Name: T-AnastaFlo

Indications for use:

The T-AnastaFlo is indicated for use in preventing ischemia by the shunting and/or perfusion of blood or cardioplegic solution distal to the anastomosis site during the construction of coronary artery bypass grafts.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K990396

Prescription Use X OR Over-The-Counter Use____

(Per 21 CFR 801.109)