



JUN 18 1997

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Jason Smith
Regulatory Affairs Coordinator
3M Health Care
Cardiovascular Systems
Sarns and CDI Products
6200 Jackson Road
Ann Arbor, Michigan 48103-9300

Re: *K964373

Sarns Arterial Cannulae with Duraflo® Treatment
Regulatory Class: II (Two)
Product Code: 74 DWF
Dated: April 9, 1997
Received: April 10, 1997

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 - Mr. Jason Smith

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 "dsmo@fdadr.cdrh.fda.gov."

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): K 964373/5001

Device Name: Sarns Arterial Cannulae with Duraflo Treatment

Indications For Use:

The Sarns Aortic Arch Cannulae with Duraflo Treatment, Flexible Arterial Cannulae with Duraflo Treatment, High Flow Aortic Arch Cannulae with Duraflo Treatment, Soft Arc Cannula with Duraflo Treatment, D4 Cannulae with Duraflo Treatment, and the Soft Flow Cannulae with Duraflo Treatment are indicated for use in perfusion of the ascending aorta during cardiopulmonary bypass surgery.

The Sarns Flexible Aortic Arch Cannula with Duraflo Treatment is indicated for use in perfusion of the descending thoracic aorta during cardiopulmonary bypass surgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Alana Shearer / Adina
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K 964373

Prescription Use
(per 21 CFR 801.109)

OR

Over-The-Counter Use

JUN 18 1997

510(k) SUMMARY

K964373

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The assigned 510(k) number is _____.

Submitter's Name: 3M Health Care
Submitter's Address: 6200 Jackson Road, Ann Arbor, Michigan 48103
Contact Person: Jason Smith
Phone Number: (313) 663-4145
FAX Number: (313) 663-5062
Summary Date:

Device Trade Names:

Sarns Aortic Arch Cannulae with Duraflo® Treatment, Sarns Flexible Aortic Arch Cannula with Duraflo® Treatment, Sarns Flexible Arterial Cannulae with Duraflo® Treatment, Sarns High Flow Aortic Arch Cannulae with Duraflo® Treatment, Sarns Soft-Arc Cannula with Duraflo® Treatment, Sarns D4 Cannulae with Duraflo® Treatment, Sarns Soft Flow Cannulae with Duraflo® Treatment

Device Classification Name:

"Cardiopulmonary Bypass Vascular Catheter, Cannula, or Tubing" (21 CFR 870.4210)

Predicate Devices:

The *Sarns Arterial Cannulae with Duraflo® Treatment* are substantially equivalent to the existing *Sarns Arterial Cannulae* [510(k) clearance numbers listed in the table below].

Cannula Type	510(k) Number	Clearance Date
Soft Flow	K934127	2/22/94
D4	K874896	2/2/88
Soft-Arc	K834134	4/17/84
Flexible Arterial	K771499	8/16/77
High Flow Aortic Arch	K770429	3/16/77
Aortic Arch, Flexible Aortic Arch	Preamendment	

Device Description:

The only difference between the *Sarns Arterial Cannulae* and the *Sarns Arterial Cannulae with Duraflo® Treatment* is the addition of the Duraflo® Treatment. As a result of this process, a layer of heparin is deposited on the inside and outside of the cannula tip, tube, and connector. Like their predicate devices, the *Sarns Arterial Cannulae with Duraflo® Treatment* are sterile, single-use medical devices. They are available in sizes ranging from 3.8 mm to 8.0 mm outer diameter tip sizes, with tips being straight or angled, soft or rigid, metal or plastic. Several styles of the *Sarns Arterial Cannulae* are available in both wire-reinforced and non-wire-reinforced tube styles. Other features include an

optional suture flange on some models as well as an optional Luer port for the venting of air.

Indications for Use:

The *Sarns Aortic Arch, Flexible Aortic Arch, High Flow Aortic Arch, Flexible Arterial, D4, and Soft Flow Cannulae with Duraflo® Treatment* are indicated for use in perfusion of the ascending aorta during cardiopulmonary bypass surgery. The *Sarns Flexible Aortic Arch Cannula with Duraflo® Treatment* is indicated for use in perfusion of the descending thoracic aorta during cardiopulmonary bypass surgery.

Technological Characteristics:

The only difference between the *Sarns Arterial Cannulae* and the *Sarns Arterial Cannulae with Duraflo® Treatment* is the addition of the Duraflo® Treatment. As a result of this process, a layer of heparin is deposited on the inside and outside of the cannula tip, tube, and connector. There will be no dimensional changes to the cannulae due to the addition of the Duraflo® Treatment

Nonclinical Performance:

The performance characteristics of selected models (these models were chosen as being representative of the technological attributes of all models of *Sarns Arterial Cannulae*) of the *Sarns Arterial Cannulae with Duraflo® Treatment* were exhaustively tested and compared with the performance characteristics of the currently marketed *Sarns Arterial Cannulae*. All new and existing performance characteristics of the *Sarns Arterial Cannulae with Duraflo® Treatment* have been validated.

Clinical Performance:

Clinical testing was not performed on these devices.

Conclusions from Nonclinical Tests:

The *Sarns Arterial Cannulae with Duraflo® Treatment* perform as intended according to their performance specifications. The *Sarns Arterial Cannulae with Duraflo® Treatment* are substantially equivalent to their predicate devices.