

JUN 18 1997

15964374

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMMA 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 Venous Return Catheters with Duraflor® Treatment, Sarns Right Angle Venous Return Catheters with Duraflor® Treatment, Sarns Two Stage Venous Return Catheters with Duraflor® Treatment, Sarns Venoatrial Catheters with Duraflor® Treatment, Sarns Dual Stage Venous Return Catheters with Duraflor® Treatment.

Device Classification Name:

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

Predicate Devices:

The *Sarns Venous Return Catheters with Duraflor® Treatment* are substantially equivalent to the existing *Sarns Venous Return Catheters* [510(k) clearance numbers listed in the table below].

| Catheter Type | 510(k) Number | Clearance Date |
|---|---------------|----------------|
| 20, 24, 28, and 32 French Size (Fr.) non-wire Venous Return Catheter sizes; 8, 10, 12, 14, 16, 18, 20, 22, 24, 28, 30, and 34 Fr. wire-reinforced Venous Return Catheter sizes, Right Angle Venous Return Catheters | K905224 | 2/5/91 |
| Venoatrial Catheters | K875048 | 2/18/88 |
| Two Stage Venous Return Catheters (wire-reinforced), Dual Stage Venous Return Catheters | K810415 | 3/17/81 |
| 32, 36, and 40 Fr. wire-reinforced Venous Return Catheters | K790246 | 3/2/79 |
| Two Stage Venous Return Catheters (non-wire-reinforced) | K770431 | 3/16/77 |
| 32, 26, 40 and 51 Fr. Venous Return Catheters | Preamendment | |

Device Description:

The only difference between the *Sarns Venous Return Catheters with Duraflo® Treatment* and the *Sarns Venous Return Catheters* 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 catheter tip, tube, and connector.

As with their predicate devices, all of the *Sarns Venous Return Catheters with Duraflo® Treatment* are sterile, single-use medical devices. The *Sarns Venous Return Catheters with Duraflo® Treatment* are available in sizes ranging from 8 French to 51 French. (The French size is the outer diameter of the catheter in millimeters multiplied by three.). The *Sarns Standard and Right Angle Venous Return Catheters with Duraflo® Treatment* are available as a single tube. The *Sarns Two Stage, Venatrial, and Dual Stage Venous Return Catheters with Duraflo® Treatment* consist of two differently-sized tubes. Many different models of the *Sarns Venous Return Catheters with Duraflo® Treatment* are available with wire-reinforced tubing. Some models of the multi-stage versions of the *Sarns Venous Return Catheters with Duraflo® Treatment* have an integral connector. Additionally, the *Sarns Venous Return Catheters with Duraflo® Treatment* have been coated with heparin via the Duraflo® Treatment process.

Indications for Use:

The *Sarns Standard and Right Angle Venous Return Catheters with Duraflo® Treatment* are indicated for use in dual cannulation of the superior and inferior vena cava for venous drainage during cardiopulmonary bypass surgery. The *Sarns Two Stage Venous Return, Dual Stage Venous Return, and Venatrial Catheters with Duraflo® Treatment* are indicated for use in single tube drainage of the right atrium and vena cava during cardiopulmonary bypass surgery.

Technological Characteristics:

The only difference between the *Sarns Venous Return Catheters with Duraflo® Treatment* and the *Sarns Venous Return Catheters* 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 catheter tip, tube, and connector. There will be no dimensional changes to the catheters 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 Venous Return Catheters*) of the *Sarns Venous Return Catheters with Duraflo® Treatment* were tested and compared with the performance characteristics of the currently marketed *Sarns Venous Return Catheters*. All new and existing performance characteristics of the *Sarns Venous Return Catheters with Duraflo® Treatment* have been validated.

Clinical Performance:

Clinical testing was not performed on these devices.

Conclusions from Nonclinical Tests:

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



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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: * K964374

Sarns Venous Return Catheters 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.

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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): K964374

Device Name: Sarns Venous Return Catheters with Duraflo Treatment

Indications For Use:

The Sarns Standard Venous Return Catheters with Duraflo Treatment and the Sarns Right Angle Venous Return Catheters with Duraflo Treatment are indicated for use in dual cannulation of the superior and inferior vena cava for venous drainage during cardiopulmonary bypass surgery.

The Sarns Two Stage Venous Return Catheters with Duraflo Treatment, Venatrial Catheters with Duraflo Treatment, and the Dual Stage Venous Return Catheters with Duraflo Treatment are indicated for use in single tube drainage of the right atrium and vena cava 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)

Alma Steuben Lott
(Division Signature)

Division of Cardiovascular, Respiratory,
and Neurological Devices

(Law 510(k) Number K964374)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number

Prescription Use
Per 21 CFR 801.109)

OR

Over-The-Counter Use