OCT 2 5 2002 K022477

510(k) Summary

Summit Medical Transfusion Filter

Manufacturer

Summit Medical Ltd
Industrial Park
Bourton on the Water
Gloucestershire
GL54 2HQ
United Kingdom

Contact

James Bradbury
Regulatory Affairs Manager
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Device Name

Transfusion Filter

Classification Name

Microfilter, Blood Transfusion

Predicate Product

SQ40 Blood Transfusion Filter, Pall Biomedical Products Co. (K960993)

Product Description

The Transfusion Filter device consists of a sterile, single wrapped package, containing a filter assembly, with or without an administration set. The administration set is fitted with a drip chamber and roller clamp.

The filter unit is connected to a flexible bag containing the blood to be reinfused via a spike port in the bag. The filter is primed by holding the bag inverted, with the filter above the bag, then squeezing the bag to

force blood through the filter medium and to the desired level within the drip chamber.
The roller clamp is then closed, and the system hung on a drip stand ready for use. The administration line can then be primed and connected to the patient according to clinical practice, and the rate of blood flow to the patient regulated by adjusting the roller clamp.

Substantial Equivalence

The Summit Medical Transfusion Filter is substantially equivalent specifically to the Pall Biomedical Products Co. SQ40 Blood Transfusion Filter (K960993), in that they are designed with the same design principles, made of the same materials, and have the same indications and contraindications for use.

Indications for Use

The Summit Medical Transfusion Filter is intended for the filtration of up to one unit of intra-operative or post-operative salvaged blood, for the reduction of lipid particles, anaphylatoxin C3a, microaggregates and leucocytes. It is indicated for the reinfusion of blood derived from the surgical site or post-operative wound drainage.

Safety and Effectiveness

Performance testing carried out includes bubble point testing, pressure leak tests, particulate cleanliness, mechanical and hydrostatic testing of bonded joints, microbiological bioburden and endotoxin validation.

The device is Gamma sterilised, validation of which was carried out in accordance with ISO 11137.

Biocompatibility testing was carried out in accordance with ISO 10993, and includes Cytotoxicity, Sensitization, Irritation or Intracutaneous Reactivity, Acute Systemic Toxicity and Haemocompatibility.

The test results achieved demonstrate that the device meets the applicable standards, is biocompatible, and performs in accordance with design specifications.

No safety or effectiveness issues are raised when the Summit Medical Transfusion Filter is compared with the predicate product, and therefore the Summit Medical Transfusion Filter is substantially equivalent to the Pall SQ40 Blood Transfusion Filter (K960993).

James Bradbury

James Bradbury
Regulatory Affairs Manager
Summit Medical Ltd.

Date: 25 July 2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 2002

Summit Medical Ltd.
c/o Mr. Neil R. Armstrong
MeddiQuest Ltrd.
Business and Technology Centre,
Bessemer Drive,
Stevenage, SG1 2DX
United Kingdom

Re: K022477
Summit Medical Transfusion Filter
Regulation Number: 880.5440
Regulation Name: Microfilter, Blood Transfusion
Regulatory Class: II (two)
Product Code: 74 CAK
Dated: July 26 2002
Received: July 29 2002

Dear Mr. Armstrong:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

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: _____

Device Name: **Summit Medical Transfusion Filter**

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Division of Cardiovascular & [illegible] Devices

510(k) Number K041477

Prescription Use ✓ OR Over-the-counter Use _____

(Per 21 CFR 801.109)

Description

The transfusion filter is a free-flow, low priming volume device which provides a 40 micron absolute rated screen filter medium for the removal of potentially harmful blood component microaggregates and non-blood component particulate matter.

Indications

Transfusion of stored blood, packed red cells, platelet and granulocyte concentrations and filtration of ViaSpan® (Cold Storage Solution).*

* ViaSpan® is a registered trademark of Dupont-Merck.