K024097

FEB 14 2003

Summit Medical Ltd

510(k) Premarket Notification

for the

CellTrans™ Postoperative Autotransfusion Set

Attachment 7

510(k) Summary

510(k) Summary

Summit Medical CellTrans™ Postoperative Autotransfusion Set

Manufacturer

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

Contact

James Bradbury
Regulatory Affairs Manager

Phone: 011 (44) 1451 821311
Fax: 011 (44) 1451 821092
E-mail: **james.bradbury@summit-medical.co.uk**

Device Name

CellTrans™ Postoperative Autotransfusion Set

Classification Name

Autotransfusion Apparatus

Predicate Product(s)

- Summit Medical CellTrans™ Postoperative Autotransfusion System (K022489)
- Summit Medical Transfusion Filter (K022477)

Product Description

The CellTrans™ Postoperative Autotransfusion Set consists of two individually sterilized packages, containing the Summit Medical CellTrans™ Postoperative Autotransfusion System (K022489) and the Summit Medical Transfusion Filter (K022477) respectively, presented for ease of handling and reordering in a non-sterile, polyethylene slide lock transit bag. Inside the transit bag the CellTrans™ device is double-wrapped, whilst the Transfusion Filter is single wrapped, both using Tyvek & Film packaging.

The transit bag also contains an additional copy of the CellTrans™ Instructions For Use to facilitate use of the Transfusion Filter.

Substantial Equivalence

The Summit Medical CellTrans™ Autotransfusion Set is substantially equivalent to the Summit Medical CellTrans™ Autotransfusion System (K022489) and Summit Medical Transfusion Filter (K022477).

Indications for Use

The Summit Medical CellTrans™ Postoperative Autotransfusion Set is intended for the collection, filtration and reinfusion of blood lost postoperatively following surgery, particularly orthopaedic joint replacement.
The device is indicated for autologous blood transfusion.

Safety and Effectiveness

No safety or effectiveness issues are raised when the Summit Medical CellTrans™ Postoperative Autotransfusion Set is compared to the predicate products and therefore the CellTrans™ Postoperative Autotransfusion Set is substantially equivalent to the Summit Medical CellTrans™ Postoperative Autotransfusion System and the Summit Medical Transfusion Filter.

04.12.02

James Bradbury
Regulatory Affairs Manager
Summit Medical Ltd.

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 14 2003

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

Re: K024097
Trade Name: Summit Medical CellTrans™ Postoperative Autotransfusion Set
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion Apparatus
Regulatory Class: Class II (two)
Product Code: CAC
Dated: December 4, 2002
Received: December 12, 2002

Dear Mr. Armstrong:

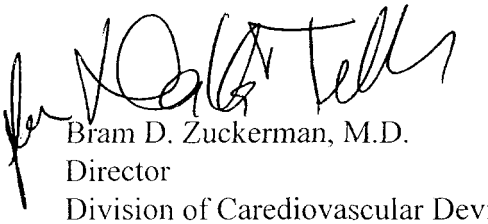
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (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 Carediovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K024097

Device Name: **Summit Medical CellTrans™ Postoperative Autotransfusion Set**

Indications for Use:

The Summit Medical CellTrans™ Postoperative Autotransfusion Set is intended for the collection, filtration and reinfusion of blood lost postoperatively following surgery, particularly orthopaedic joint replacement. The device is indicated for autologous blood transfusion.

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K024097

Prescription Use X OR Over-the-counter Use _____

(Per 21 CFR 801.109)