510(k) Summary

Summit Medical CellTrans™ Postoperative Autotransfusion Device

Manufacturer

Summit Medical Ltd
Industrial Park
Bourton on the Water
Gloucestershire
GL54 2HQ
UK.

Contact

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Regulatory Affairs Manager

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Device Name

CellTrans™ Postoperative Autotransfusion Transfusion System

Classification Name

Autotransfusion Apparatus

Predicate Product

Betatrans Orthopaedic Autotransfusion System (K951592), Duxbury Scientific Inc.

Product Description

The CellTrans™ device consists of a sterile, double wrapped package, containing two needle and drain assemblies, a blood collection assembly with patient drain connection line and a compressible bellows collection vessel with twin outlet ports, and two blood Transfer bags. The patient and transfer bag lines are fitted with pinch clamps, and in addition the transfer bag connection luers are fitted with sealing caps, for use after a

filled bag is removed from the collection vessel. The collection bellows and transfer bags are fitted with non-return valves to prevent backflow of exudate to the patient.

The drains are placed in the patient, and connected to the collection system via the twin drain Y-connector. The transfer bags are fitted to the collection vessel outlet ports. Blood collection is initiated by compressing the bellows to apply a low vacuum to the wound, the collected blood then transferring into one of the transfer bags, via the gross filter. When the bag is full, or in accordance with the American Association of Blood Banks Guidelines for Blood Recovery and Reinfusion in Surgery (AABB), the bag can be removed from the collection system, and transferred for reinfusion to the patient. Blood collection can continue with the second transfer bag.

Following use of the second bag, the device can be used as a wound drainage device if this is clinically desirable, by draining into a standard wound drainage bag.

Substantial Equivalence

The Summit Medical CellTrans™ Postoperative Autotransfusion System is substantially equivalent to a number of legally marketed Autotransfusion systems, specifically the Duxbury Scientific Inc. Betatrans Orthopaedic Autotransfusion system (K951592), in that they are designed with the same design principles, made of similar materials, and have the same indications and contraindications for use.

Indications for Use

The Summit Medical CellTrans™ Postoperative Autotransfusion System is intended for the collection for reinfusion of blood lost by a patient following surgery including but not limited to orthopaedic joint replacement. The device is indicated for autologous blood transfusion.

Safety and Effectiveness

Performance testing carried out includes vacuum testing, pressure leak decay tests, functional testing using both water and time-expired blood, mechanical testing of bonded joints, microbiological bioburden and endotoxin validation.

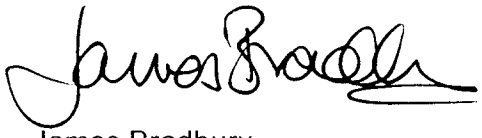
The CellTrans™ device is Gamma sterilised, validation of which was carried out in accordance with ISO 11137 and EN552.

Biocompatibility testing was carried out in accordance with ISO 10993 and FDA Blue Book Memo G95-1, including Cytotoxicity, Sensitization, Irritation or Intracutaneous Reactivity, Acute Systemic Toxicity, Subchronic Toxicity and Haemocompatibility.

Detailed Haemocompatibility testing was carried out in accordance with ISO 10993-4, with the focus of the testing on the evaluation of a number of blood cell parameters, comparing blood collected and passed through the CellTrans™ system with homologous (banked) blood.

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

No safety or effectiveness issues are raised when the Summit Medical CellTrans™ is compared with the predicate product, and therefore the Summit Medical CellTrans™ is substantially equivalent to the Duxbury Scientific Betatrans Orthopaedic Autotransfusion System (K951592).



25. July 2002

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

OCT 0 9 2002

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

Re: K022489
Cell Trans™ Postoperative Autotransfusion System
Regulation Number: 868.5830
Regulation Name: Autotransfusion Apparatus
Regulatory Class: II (two)
Product Code: CAC
Dated: July 26, 2002
Received: July 29, 2002

Dear Mr. Armstrong:

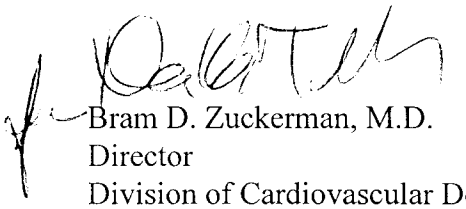
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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: K022489

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

Indications for Use:

The Summit Medical CellTrans™ Postoperative Autotransfusion System is intended for the collection for reinfusion of blood lost by a patient following surgery including but not limited to 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)

Prescription Use X OR Over-the-counter Use _____

(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K022489