SEP - 6 2011

510(k) SUMMARY

K112245

SUBMITTER:	Sorin Group Italia S.r.l. 86, Via Statale 12 Nord 41037 Mirandola (MO) Italy
CONTACT PERSON:	Luigi Vecchi Phone: 39 0535 29811 Fax: 39 0535 25229
DATE PREPARED:	August 4, 2011
DEVICE TRADE NAME:	XTRA
COMMON NAME:	Autotransfusion System
CLASSIFICATION NAME:	Apparatus, Autotransfusion
UNMODIFIED DEVICE:	XTRA Autotransfusion System (#K101586)
Classification Product Code	CAC
Regulation Number	868.5830

DEVICE DESCRIPTION:

XTRA is an Autotransfusion System designed to recover shed blood during intraoperative and postoperative procedures and for collection of platelet poor plasma (PPP) and platelet rich plasma (PRP) in preoperative procedures.
It is a software-controlled device provided with disposable and hardware elements that include the following major components: centrifuge, blood pump, automatic clamps, control and monitoring sensors, and an user interface (display panel and keyboard).

The modified device is a software upgraded version (SW 1.0.2.0) of the unmodified device.

Besides fixing the software bugs, the main differences introduced with the new SW upgrade consist of: change of the parameters of the Pstd intraoperative factory protocol (when a 225 mL bowl size is used for blood processing); change of the table related to hematocrit measurement, when Heparin is used as anticoagulant; addition of Sorin Group Deutschland GmbH as supplementary manufacturing site for the device. Labeling has been also generally updated.

INDICATION FOR USE:

The XTRA Autotransfusion System is indicated for intraoperative and postoperative recovery of blood, washing of the processed blood and preoperative sequestration (with indirect patient connection). Typical clinical applications of autotransfusion include the following surgical specialties: Cardiovascular, Orthopedics, Thoracic, Transplant Surgery, Emergency (Trauma), Neurosurgery, Obstetrics and Gynecology, and Urology.

TECHNOLOGICAL CHARACTERISTICS:

The modified device XTRA with software 1.02.0 has the same materials, fundamental scientific technology, operating principles and control mechanisms of the unmodified device.

Compared to the unmodified device, XTRA with software 1.02.0 is manufactured with the same manufacturing steps and is provided with the same hardware components.

No change to the intended use has been made as a result of the modifications.

There are no differences in packaging type and material between unmodified and modified device.

The disposable provided with both modified and unmodified devices is ethylene oxide sterilized and have a non-pyrogenic fluid path. It is for single use only.

Sorin Group Italia S.r.l. believes that the XTRA with software 1.02.0 is substantially equivalent to the unmodified device and to other currently marketed automated autotransfusion devices, that any differences are minor, and raise no new issues of safety and effectiveness.

NON CLINICAL TEST RESULTS:

Applicable tests were carried out in accordance with the requirements of ISO 10993-1 and the FDA May 1st, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing of raw materials.

The disposable designed for the modified device XTRA with software 1.02.0 is identical to the disposable provided with the unmodified device (#K101586) and is characterized by the same materials in blood contact.
As no new materials are used, this 510(k) cross references biocompatibility data for the unmodified device, the XTRA Autotransfusion System (#K101586).

IN VITRO TEST RESULTS:

In vitro testing was performed in order to provide the data necessary to demonstrate both the substantial equivalence with the unmodified device and also to comply with safety and effectiveness requirements.
Comparative tests were performed according to internal methods developed by the manufacturer.

The results of these tests met established performance specifications.

CONCLUSIONS:

The results of *in vitro* studies demonstrate that the XTRA with software 1.02.0 is substantially equivalent to the unmodified device in terms of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Sorin Group Italia S.r.l.
c/o Mr. Barry Sall
195 West Street
Waltham, MA 02451

SEP - 6 2011

Re: K112245
Trade/Device Name: XTRA Autotransfusion System
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion apparatus
Regulatory Class: II
Product Code: CAC
Dated: August 4, 2011
Received: August 4, 2011

Dear Mr. Sall:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K112245

Device Name: XTRA Autotransfusion System
Indication for Use:

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- Cardiovascular
- Orthopedics
- Thoracic
- Transplant Surgery
- Emergency (Trauma)
- Neurosurgery
- Obstetrics and gynecology
- Urology

Prescription Use___X____
(Part 21CFR 801 Subpart D)

Over-the- Counter Use_____
AND/OR (21 CFR 807 Subpart C)

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

(Division Sign-Off)
Division of Cardiovascular Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K112245