STERIS®

MAR 2 0 2009

510(k) Summary
For
STERIS®5085 SRT

STERIS Corporation
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Contact: John R. Scoville.
Fellow
Regulatory Affairs
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Summary Date: March 05, 2009
Submission: K090136

1. Device Name

Trade Name:	STERIS® 5085 SRT
Common/Usual Name:	STERIS® 5085 SRT Surgical Table
Classification Name:	Operating Table classified as Class I device (Product Code [FQO] per 21 CFR 878.4960

2. Predicate Devices

- K041924 Hausted POWERTRAN Series Stretcher
- K971307 Amsco 3085SP Surgical Table
- K022309 Stryker ZOOM motorized Stretcher

3. Description of Device

The STERIS® 5085 SRT Surgical Table is a mobile, electro-hydraulically operated surgical table designed to support all general surgical procedures including cardiac and vascular, endoscopic, gynecology, urology, nephrectomy, neurology, ophthalmology and orthopedics with the addition of STERIS table accessories. The STERIS® 5085 SRT Surgical Table features powered lateral tilt, Trendelenburg / reverse Trendelenburg, Zip-Slide™ movable tabletop, and adjustable height functions. The STERIS® 5085 SRT has a patient transport feature that allows the user to transport patients to and from the surgical suite on hard levelsurfaces.

4. Intended Use

The STERIS® 5085 SRT is a general surgical table with high patient weight capacity, extended width capability, and lower minimal table top elevation. The STERIS® 5085 SRT accommodates all general surgical procedures including but not limited to, cardiac and vascular, endoscopic, gynecology, urology, nephrectomy, neurology, ophthalmologic, orthopedics and other procedures requiring intraoperative fluoroscopic C-arm imaging and also supports laparoscopic surgical technique for the largest surgical patients.

The STERIS® 5085 SRT enables patient transport on hard level surfaces within the surgical suite (from pre-operative areas to the operating room and again from the operating room to post operative recovery).

5. Description of Safety and Substantial Equivalence

STERIS Corporation believes that the STERIS® 5085 SRT Surgical Table is Substantially Equivalent to the predicate devices: K041924 Hausted POWERTRAN Series Stretcher, K971307 Amsco 3085SP Surgical Table and K022309 Stryker ZOOM motorized Stretcher and the differences between the proposed and predicate devices do not raise any new issues of safety and efficacy.

The STERIS® 5085 SRT Surgical Table as well as the predicate devices have been designed to meet UL and IEC requirements. Significant safety and performance characteristics are tested to ensure compliance with specifications and that the proposed device is as safe, as effective, and performs as well as or better than the predicate devices. No performance standards or special controls applicable to powered table patient transport devices have been established under sections 513 or 514 of the FD& C Act.

The proposed device also complies with the following voluntary standards:

UL 60601-1 (Amended by UL 60601-1 Rev 1, UL 60601-1): Medical Electrical Equipment, Part 1: General Requirements for Safety

EN/IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance for Medical Electrical Equipment, Part 1: General Requirements for Safety

EN/IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

EN/IEC 60601-1-4: Medical electrical equipment - Part 1-4: General requirements for safety - Collateral Standard: Programmable electrical medical systems.

EN/IEC 60601-1-6: Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability .

EN/IEC 60601-2-46: Medical electrical equipment - Part 2-46: Particular requirements for the safety of operating tables.

CAN/CSA C22.2 No. 601.1-M90: Medical Electrical Equipment - General Requirements for Safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Steris Corporation
% Mr. John R. Scoville, Jr.
Fellow, Regulatory Affairs
5960 Heisley Road
Mentor, Ohio 44060-1834

MAR 2 0 2009

Re: K090136
Trade/Device Name: STERIS® 5085 SRT
Regulation Number: 21 CFR 878.4960
Regulation Name: Operating tables and accessories and operating chairs and accessories
Regulatory Class: I
Product Code: FQO
Dated: March 5, 2009
Received: March 6, 2009

Dear Mr. Scoville:

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.

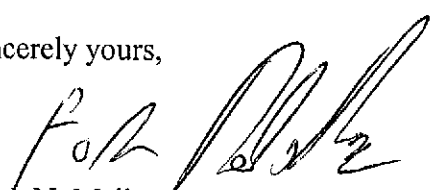
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090136

Indications for Use

510(k) Number (if known): K090136

Device Name: STERIS® 5085 SRT

Indications For Use:

The STERIS® 5085 SRT is a general surgical table with high patient weight capacity, extended width capability, and lower minimal table top elevation. The STERIS® 5085 SRT accommodates all general surgical procedures including but not limited to, cardiac and vascular, endoscopic, gynecology, urology, nephrectomy, neurology, ophthalmologic, orthopedics and other procedures requiring intraoperative fluoroscopic C-arm imaging and also supports laparoscopic surgical technique for the largest surgical patients.

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. O'Leary for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K090136