stryker® K970714

4100 East Milham Avenue
Kalamazoo, MI 49001-6197
(616) 323-7700 (800) 253-3210

DEC 16 1997

Device Name:

Classification Name:	Autotransfusion Apparatus: 21 CFR 868.5830, Class II
Common/Usual Name:	Postoperative Autotransfusion Device
Proprietary Name:	Stryker ConstaVac Blood Conservation System II (CBCII)

Device Sponsor:

Stryker Corporation
Instruments Division
4100 E. Milham Avenue
Kalamazoo, MI 49001
Registration No: 1811755

Regulatory Class: Class II

Summary of Safety and Effectiveness:

The Stryker ConstaVac Blood Conservation System II (CBCII) is an autologous blood recovery system intended for the post-operative collection and filtration of blood from a surgical wound in order to transfuse the whole blood back to the patient.

The Stryker CBCII System is a single patient use, sterile, disposable, autotransfusion apparatus. The system consists of a wound drain and evacuator tube, an 800cc blood collection reservoir, a means for providing a vacuum in which to drain the blood from the wound site, a means for transferring the blood to a reinfusion bag and a reinfusion bag. The blood disposal bag provides a means for the user to dispose of wound drainage collection once reinfusion has been discontinued.

This reinfusion device has been tested and does meet the applicable sections of the American National Standard for Auto Transfusion Devices, ANSI/AAMI AT6-1981 as well as the biocompatibility guidelines set forth in the Tripartite Guidance.

The CBCII System is equivalent to existing marketed products by companies such as Baxter V. Mueller. Power modality, intended use, and safety risks are all substantially equivalent. The CBCII Blood Disposal Bag is equivalent to existing marketed products by companies such as Zimmer. Intended use and safety risks are substantially equivalent.

The Stryker CBC II System, including the blood disposal bag, does not raise any new safety and efficacy concerns when compared to similar legally marketed devices. Therefore, the Stryker CBC II System is substantially equivalent to these existing devices.

Tammy Lounds
Assoc. Manager, Regulatory Affairs
Stryker Instruments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Rockville MD 20857

Mr. Rodney Parker
Microbiologist and Supervisor
of Regulatory Affairs
Stryker Instruments
4100 East Milham Avenue
Kalamazoo, MI 49001

DEC 16 1997

Re: K970714
Stryker Constavac Blood Conservation System II
Regulatory Class: II (Two)
Product Code: CAC
Dated: October 15, 1997
Received: October 22, 1997

Dear Mr. Parker:

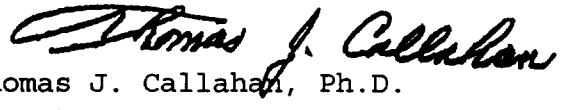
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html."

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

868.5830 - CAC II - Autotransfusion Apparatus

510(k) Number (if known): K 970714

Device Name: CBCII Blood Disposal Bag

Indications For Use:

The Stryker ConstaVac Blood Conservation System II (CBCII) Disposal Blood Bag is used with the previously cleared CBC II System to provide a disposal method for wound drainage collected in the CBCII reservoir.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K 970714

Prescription Use ✓ OR Over-The- Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)