Summary of Safety and Effectiveness

Submitter:	Zimmer Orthopaedic Surgical Products 200 West Ohio Avenue P.O. Box 10 Dover, Ohio 44622
Contact Person:	Cindy J. Dickey Regulatory Compliance Manager Telephone: (330) 364-9493 Fax: (330) 364-9490
Date:	June 4, 2004
Trade Name:	*HEMOVAC*® BLOOD REINFUSION SYSTEM
Common Name:	Autotransfusion System
Classification Name and Reference:	Apparatus, Autotransfusion 21 CFR § 868.5830
Predicate Devices:	Zimmer *Hemovac*® Autotransfusion System, manufactured by Zimmer Orthopaedic Surgical Products, K920273, cleared January 28, 1993 CBC II Constavac™ Autotransfusion System, manufactured by Stryker®, K952224, cleared November 17, 1995 Suretrans™ Autotransfusion System, manufactured by Davol®, K913247 or 914119, cleared February 25, 1993 or December 3, 1992
Device Description:	The *HEMOVAC*® Blood Reinfusion System is a sterile, single patient use, closed, disposable system intended for post operative collection, filtration, and reinfusion of autologous blood. The system consists of a wound drain and trocars, blood lines, graduated 800ml blood collection reservoir (contains pre-filter, air filter, fat retention valve), *Hemovac*® evacuator, anticoagulant port, transfer tube, and blood reinfusion bag.

The wound is drained utilizing suction created by activating the *Hemovac*® evacuator. Blood passes through the drain, blood line tubing, and into the collection reservoir (pre-filter located inside of collection reservoir).

Anticoagulant may be added through the injection port located in the blood line. Anticoagulant therapy is administered at the discretion of the physician.

To reinfuse the collected blood back to the patient, the blood is transferred from the collection reservoir to the reinfusion bag via gravity feed. A fat retention valve (located inside of the collection reservoir) is designed to retain the top portion of the collected blood which may contain fats. The blood bag is spiked with a standard patient administration set that contains a 20-40 micron filter (not supplied with the system), and the blood bag is gravity reinfused to the patient per hospital/AABB guidelines.

The process is repeated for additional collection/reinfusions. After collection for reinfusion is no longer desired, the system can be converted to straight drainage for disposal only. The *Hemovac*® evacuator is removed from the collection reservoir and reconnected to the blood line assembly. An accessory infection control bag (not supplied with the system) may be used to empty the contents of the evacuator. This is used for disposal only.

Indications for Use:

The *Hemovac*® Blood Reinfusion System is a closed system intended for post operative collection, filtration, and reinfusion of autologous blood. It is the responsibility of the physician to determine if this therapy is appropriate for a specific procedure.

Comparison to Predicate Device:

The *Hemovac*® Blood Reinfusion system is substantially equivalent to the legally marketed

	autotransfusion systems, specifically the Stryker® CBC II Constavac™, Davol® Suretrans™, and the Zimmer *Hemovac*® Autotransfusion in that the devices are similar in design, materials, and indications for use.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: This device has been tested and does meet the applicable sections of the American National Standard for Autologous Transfusion Devices, ANSI/AAMI AT6-1991, as well as ANSI/AAMI/ ISO 10993-1:1997, "Biological evaluation of Medical Devices." Hemocompatibility was conducted in accordance with AAMI/ANSI/ ISO 10993-4:2002. Clinical Performance and Conclusions: Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 14 2004

Zimmer Orthopaedic Surgical Products
c/o Ms. Cindy J. Dickey
Regulatory Compliance Manager
200 West Ohio Avenue
P.O. Box 10
Dover, OH 44622

Re: K041525
Trade/Device Name: *Hemovac*® Blood Reinfusion System
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion apparatus
Regulatory Class: II
Product Code: CAC
Dated: June 4, 2004
Received: September 22, 2004

Dear Ms. Dickey:

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 (240) 276-0120. 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,

Donna R. Lochner

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 (if known): K041525

Device Name:

Hemovac® Blood Reinfusion System

Indications for Use:

The HEMOVAC® Blood Reinfusion System is a closed system intended for post operative collection, filtration, and reinfusion of autologous blood. It is the responsibility of the physician to determine if this therapy is appropriate for a specific procedure.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lechner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041525