K063582

zimmer

Traditional 510(k) Premarket Notification

Summary of Safety and Effectiveness

APR 26 2007

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:	November 28, 2006
Trade Name:	*Zimmer*™ Cut Resistant Glove Liners
Common Name:	Glove Liner
Classification Name and Reference:	Surgeon's Glove (accessory to) 21 CFR § 878.4460
Predicate Device:	Cut Resistant Surgical Glove Liner, manufactured by Wells Lamont, K922407, cleared June 15, 1993
Device Description:	While cut resistant glove liners do not protect against punctures, especially punctures presented by means of sharp needles or sharp instrument tips, they will provide moderate protection against cuts and abrasion. Cut resistant glove liners have been shown to reduce the risk of inner glove perforations and reduce the risk of contamination from patient's blood.[2] Even with the limitations, researchers still recommend the use of cut resistant glove liners when bone fragments are being manipulated or when using sharp instruments.[1] The *Zimmer* Cut Resistant Glove Liner is designed to provide the surgeon, assistant, scrub nurse or any surgical arena personnel extra protection in the event of an accidental cut when used as a liner to a surgical glove. The *Zimmer* Cut Resistant Glove Liner is produced from high strength polyethylene.

	Both products are an ultra high molecular weight polyethylene that offers high cut resistance. Either manufactured fiber will provide compliant cut resistance when tested in accordance to ASTM1790-04.
Indications for Use:	The *Zimmer* Cut Resistant Glove Liners are intended to provide moderate cut resistance when used with an inner and outer surgical glove. The glove liner should be worn between two surgical gloves.
Comparison to Predicate Device:	The *Zimmer* Cut Resistant Glove Liners are substantially equivalent to the legally marketed glove liners, specifically the Wells Lamont Cut Resistant Glove Liners in that the devices are similar in design, materials, and indications for use. The Wells Lamont Cut Resistant Glove Liners are cut resistant gloves, which provide protection from cuts, slashes, and sharp instruments. For optimum barrier protection, it is suggested that a surgical glove be worn over and under Spec-Tec Cut resistant gloves. Both the proposed and predicate devices are offered in a variety of sizes. Sizing is depicted with color coded cuff bands.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: Non-clinical performance data was demonstrated to meet the ASTM 1790-04 requirements for cut resistance. The glove liners were tested in accordance with ANSI/AAMI/ISO 10993-1:1997, "*Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing*".
Performance Data (Nonclinical	Non-Clinical Performance and Conclusions:

and/or Clinical):	
	The Guidance for Industry and FDA, "Medical Glove Guidance Manual." was consulted.
Performance Data (Nonclinical and/or Clinical):	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

Ms. Cindy J. Dickey
Regulatory Compliance Manager
Zimmer, Incorporated
Zimmer Orthopaedic Surgical Products
200 West Ohio Avenue
P.O. Box 10
Dover, Ohio 44622-0010

APR 26 2007

Re: K063582
Trade/Device Name: Zimmer™ Cut Resistant Glove Liners
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: March 30, 2007
Received: April 4, 2007

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) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063582

Device Name:

Zimmer™ Cut Resistant Glove Liners

Indications for Use:

The *Zimmer* Cut Resistant Glove Liners are intended to provide moderate cut resistance when used with an inner and outer surgical glove. The glove liner should be worn between two surgical gloves.

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

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila A. Murphy M.D.
(Digitally Signed)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K063582