

MAR - 4 2004

K033842

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510(k) Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness for the Nubert, Albert and Hubert Impervious Bags is submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990 and follows the Office of Device Evaluation (ODE) guidance concerning the organization and content of a 510(k) summary.

Applicant:

Vernon-Carus Limited
Penwortham Mills
Preston, Lancashire PR1 9SN
United Kingdom

Mr. Alan Davies
Group Regulatory Affairs Manager

Contact Person:

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Preparation Date:

14 November 2003

Device Trade Name:

Nubert, Albert and Hubert Impervious Bags for
the Endoscopic Retrieval of Tissue

Common Name:

Laparoscopic Specimen Retrieval Bag

Classification Name:

Laparoscopic, General and Plastic Surgery
21 CFR 876.1500

Predicate Devices:

- Mtp Endobag® Disposable Extraction Bag (K990912);
- LiNA-Bag (K030422)

Device Description:

Single-use disposable device used as a receptacle for the collection and extraction of tissue during laparoscopic surgical procedures.

Intended Use of the Device:

The Nubert, Albert and Hubert impervious bags for endoscopic retrieval of tissue are single-use disposable devices used as receptacles for the collection and extraction of tissue during laparoscopic surgical procedures. There are three sizes of impervious bags for the endoscopic retrieval of tissue: NUBERT (a new bag for the endoscopic retrieval of tissue), ALBERT (a large bag for the endoscopic retrieval of tissue), and HUBERT (a huge bag for the endoscopic retrieval of tissue).

Substantial Equivalence to Predicate Devices:

The Nubert, Albert and Hubert Impervious Bags for the Endoscopic Retrieval of Tissue are substantially equivalent in design and materials to the listed predicate devices.



MAR - 4 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vernon-Carus Limited
c/o Mr. C. Robert Payne, Jr., P.E.
CRP Enterprises
P.O. Box 2608
Morgan Hill, California 95038

Re: K033842

Trade/Device Name: Nubert, Albert and Hubert Impervious Bags
for the Endoscopic Retrieval of Tissue

Regulation Number: 21 CFR 876.1500

Regulation Name: Endoscope and accessories

Regulatory Class: II

Product Code: GCJ

Dated: November 14, 2003

Received: December 10, 2003

Dear Mr. Payne:

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.

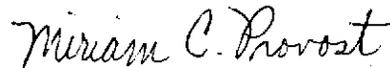
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 - Mr. C. Robert Payne, Jr., P.E.

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 (301) 594-4659. 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,



for

Celia M. Witten, Ph.D., M.D.
Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K033842

Device Name: Nubert, Albert and Hubert Impervious Bags for the Endoscopic Retrieval of Tissue

Indications for Use:

The family of impervious bags for endoscopic retrieval of tissue are single-use disposable devices used as receptacles for the collection and extraction of tissue during laparoscopic surgical procedures. The family includes three sizes of impervious bags for the endoscopic retrieval of tissue: NUBERT (a new bag for the endoscopic retrieval of tissue), ALBERT (a large bag for the endoscopic retrieval of tissue), and HUBERT (a huge bag for the endoscopic retrieval of tissue).

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(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)

Miriam C. Provost
(Division Sign-Off)
**Division of General, Restorative,
and Neurological Devices**

510(k) Number K033842