DEC 1 9 2003 K032893

December 5, 2003

Summary of safety and efficacy

Shelhigh En*Cuff* Patch

Applicant: Shelhigh Inc.
650 Liberty Ave,
Union, NJ 07083

Contact person: Shlomo Gabbay, MD
Tel: 908-206-8906
Fax 908-206-8725

I. **Proprietary and Common Name:**

Trade name:	Shelhigh *No-React*® EnCuff Patch
Common name :	Surgical Mesh
Classification:	878.3300 – Surgical Mesh
Product Code:	79 FTM

II. **Predicate Devices:**

The Shelhigh En*Cuff* Patch is Identical to the Shelhigh *No-React*® *pericardial* patches currently manufactured by Shelhigh Inc.

Intended Use

The Shelhigh En*Cuff* patch is intended for the surgical repair of soft tissue deficiencies and/or to reinforce soft tissues where weakness exists and in rotator cuff repair surgery.

IV. **Product Description**

The Shelhigh En*Cuff* is a cross-linked Xenograft pericardium, rinsed with *No-React*® anticalcification process. The device is provided sterile in 2% benzyl alcohol solution,.

VI. **Substantial Equivalence**

It is substantially equivalent to the predicate devices, having the same intended use and technological characteristics.

VII Shelhigh En*Cuff* material exhibits good tensile strength, shrink temperature and suture retention. The material reapproximates well around suture holes. It is soft and pliable. The material exhibits excellent biocompatibility, and passed the requirements of all tests

Conclusions: This device is, in respect to intended use and technological characteristics, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2003

Shlomo Gabbay, M.D.
Medical Director
Shelhigh, Inc.
650 Liberty Avenue
Union, New Jersey 07083

Re: K032893
Trade/Device Name: Shelhigh No-React ® EnCuff Patch
Regulation Number: 21 CFR 878.3300
Regulation Name: Polymeric surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: September 16, 2003
Received: September 30, 2003

Dear Dr. Gabbay:

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 (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,

Miriam C. Provost

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

K032893

Indications for Use

510(k) Number (if known):

Device Name:

Indications For Use:

The En*Cuff* is intended for use in general surgical procedures for reinforcement of soft tissue where weakness exists. The device is intended to act as a non resorbable scaffold to assist with a soft tissue repair. The device is also intended for reinforcement of the soft tissues which are repaired by suture or suture anchors, to the supraspinatus, during rotator cuff repair surgery.

Prescription Use X AND/OR Over-The-Counter Use _____
(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)

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

510(k) Number K032893