K982101

MAY - 2 2000

Class II 510(K) Summary

Shelhigh *No-React® Dura Shield*

This summary of the 510(k) information is being submitted as required by section 807.92(a).

I. Proprietary and Common Name:

Proprietary name: Patch is the Shelhigh *No-React®Dura Shield*
Common name : Dura Substitute

II. Regulatory Class:

Class II device

III. Intended Use

The device is intended for use as a dura Substitute for closure of dura mater during neurosurgery.

V. Product Description

The Shelhigh *No-React®* dura Substitute is a glutaraldehyde fixed sheet of bovine pericardium.rinsed with the detoxification process *No-React®.* The device is provided sterile in a 2% benzyl alcohol solution, packaged in a glass jar.
The material exhibits good tensile strength, shrink temperature and suture retention. The material reapproximates well around suture holes. It is soft and pliable making it convenient to implant.
The material exhibits excellent biocompatibility. Bovine pericardial material has been used successfully as a tissue patch for pericardial closure. Glutaraldhyde processed bovine pericardium has a long history of success as a permanently implanted material.

VI. Substantial Equivalence

It is substantially equivalent to the Dura Guard®manufactured ny Bio-vascular and identical to the Shelhigh *No-React®* pericardial Patch manufactured by Shelhigh Inc..

VII. Comparison with Predicate Device

The Shelhigh *No-React® Dura Shield* like the Shelhigh *No-React®*pericardial patch and like the Dura guard is a glutaraldehyde cross-linked bovine pericardium membrane which exhibits substantially equivalent

physical/mechnical properties as measured by suture retention, tensile strength, and shrink temperature. The only difference is the addition of the detoxification process *No-React®*.
Extensive validation of the effectiveness of the Patch with the detoxification process, *No-React®* indicates that these differences do not pose new questions of safety and effectiveness.

VIII. Nonclinical / Animal Tests

Physical/Mechanical test information is discussed above . An animal study was conducted to evaluate Shelhigh *No-React®* vs. the conventional glutaraldehyde treated patch, the Shelhigh *No-React®* patch shows higher level of biocompatibility.

IX. Conclusions

The non clinical /Animal testing data showed that the Shelhigh *No-React®* patch has high level of cytocompatibility when compared with the conventional glutaraldehyde treated and storage. The Shelhigh *No-React®* performance in a substantially equivalent to the predicate device and there were no significant differences between the two devices which pose new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2000

Shlomo Gabbay, MD
Chief Scientific Officer
Shelhigh, Inc.
P.O. Box 884
Millburn, New Jersey 07041

Re: K982101
Trade Name: No-React® Dura Shield
Regulatory Class: II
Product Code: GXQ
Dated: February 28, 2000
Received: March 7, 2000

Dear Dr. Gabbay:

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 requirement, 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) 594-4595. 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,

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

510(k) Number (if known): K982101

Device Name: Shelhigh *No-React® Dura Shield*
Indications For Use:

The device is intended for use as a dura Substitute for closure of dura mater during neurosurgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982101