K982810

OCT 28 1998

Class II 510(K) Summary
Shelhigh *No-React®* ***VASCUPATCH™***

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

I. Proprietary and Common Name:

Proprietary name: Shelhigh *No-React®* *VascuPatch™*

Common name: Cardiovascular patch

II. Regulatory Class:

Class II device

III. Intended Use

For repair of carotid endarterectomy and vascular patch grafting.

IV. Product Description

The Shelhigh *No-React®* *VascuPatch™* is a made of glutaraldehyde fixed bovine pericardium, rinsed with the detoxification process *No-React®*. It is stored in 2% Benzyl alcohol like the Shelhigh *No-React®* pericardial patch.
The material exhibits good tensile strength, shrink temperature, excellent biocompatibility and suture retention. It is soft and pliable making it convenient to implant.
Bovine pericardial material has been used successfully as a tissue patch for pericardial closure. Glutaraldehyde processed bovine pericardium has a long history of success as a permanently implanted material.

V. Substantial Equivalence

The Shelhigh *No-React®* *VascuPatch™* is equivalent to the Knitted MiniCrimp Vascupatch manufactured by Meadox Medical, Inc. #K905496 and identical to the Shelhigh *No-React®* pericardial patch K974914 currently manufactured by Shelhigh Inc.

VI. Comparison with Predicate Device

The Shelhigh *No-React®* *VascuPatch™*. like the Shelhigh *No-React®* pericardial patch 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. They both have identical flexibility, wall thickness and both are stored in bezyle alcohol.

VII. Nonclinical / Animal Tests

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.

VIII. Conclusions

The non clinical /Animal testing data showed that the Shelhigh *No-React® VascuPatch™.* has higher level of cytocompatibility when compared with the conventional glutaraldehyde treated and storage. The *VascuPatch™* is identical to the Shelhigh *No-React® pericardial patch,* thus is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 28 1998

Shlomo Gabbay, M.D.
Chief Scientific Advisor
Shelhigh, Inc.
P.O. Box 884
Millburn, NJ 07041

Re: K982810
Shelhigh No-React® VASCUPATCH™
Regulatory Class: II
Product Code: DXZ
Dated: July 15, 1998
Received: August 11, 1998

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 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). 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. All references to the No-React® treatment or to animal studies regarding said treatment in the labeling or promotional materials/advertisements must be immediately followed by a statement that no clinical data are available which evaluate the long term impact of the detoxification treatment in humans.

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 requirements, 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) 594-4648. 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/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K982810

Device Name: Shelhigh *No-React*® ***VASCUPATCH***™
Indications For Use:

For repair of carotid endarterectomy and vascular patch grafting.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K982810

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)