K963967
Oct. 31, 1997

GLYCAR

510(K) SUMMARY

1. Official Contact Person

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2. Regulatory Consultant

Bertram Hudson
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3. Device Name

a) Trade Name

Glycar Pericardial Patch

alternative trade names possible

b) Common Name

Biological Tissue Patch

4. F.D.A. Device Classification

Class III Device - we do not believe PMA is needed

5. Predicate Device

The predicate device is the Tissue Guard™ product line, including Supple Peri-Guard™ product line (K923657), and is a tissue patch made from glutaraldehyde-treated bovine pericardium. The device is produced by Bio-Vascular Inc., 2670 Patton Rd., St. Paul, MN 55113, (800) 255-4018.

For copies of Peri-Guard™ labels, *see Figures 3 - 4 in the Addenda under Predicate Device Labeling.*

6. Product Description

a) Candidate Device Composition

The *Glycar Pericardial Patches* are made of the same material as the predicate device, the Peri-Guard™ tissue patches, which are made from glutaraldehyde-treated bovine pericardium.

See Comparison Chart, Chart 1, in Addenda under Substantial Equivalence.

b) Material Attributes

Glutaraldehyde-treated bovine pericardium is a strong, pliable, biocompatible material which is easy to handle surgically.

Glycar's glutaraldehyde-treated pericardium possesses tissue strength equaling that of the predicate device. It provides for a durable repair, replacement or reinforcement of natural soft tissue.
See in Addenda , Chart 1, Comparison Chart, under Substantial Equivalence and Breaking Strength under Supporting Data

c) Pyrogenicity

Glycar glutaraldehyde-treated bovine pericardium has been found to have negative pyrogenicity.
See in Addenda , Chart 1, Comparison Chart, under Substantial Equivalence and Pyrogenicity under Supporting Data.

d) Manufacturing Process

The manufacturing process for the *Glycar Pericardial Patches* involves the harvesting of bovine pericardium, fixation of the pericardium in glutaraldehyde, inspection and cleaning of the pericardium, selection of the pericardium for use in strip production, additional tanning of the bovine pericardium, and then cutting of the glutaraldehyde-treated bovine pericardium for the designated strip size, followed by sterilization in formaldehyde, followed then by treatment with Glycar's proprietary anti-inflammation treatment, XX. *See in Proprietary Manufacturing Material in Addenda under Confidential Information.*

Sterility is maintained by using aseptic fill under Clean Room 100 conditions, during transfer to anti-inflammation treatment and to the final storage medium, 2% propylene oxide in water.
See Outline of Manufacturing Process in Addenda under Manufacturing Information and Sterilization Information.

e) Product Sizes

Sizes and shape has not been determined at this time.

7. Intended Use of Product

a) Candidate Device Intended Use

The Glycar Inc., *Pericardial Patch* has the same intended use, pericardial closure, as the predicate device, the Bio-Vascular Inc., Peri-Guard™ patch, which is a tissue patch made from the same glutaraldehyde-treated bovine pericardium.

Already approved intended uses for the Glycar Tissue Repair Patch family of glutaraldehyde-tanned bovine pericardial tissue patches are:

The *Glycar Tissue Repair Patch* (K942911) was deemed substantially equivalent to the Peri-Guard™ bovine pericardial tissue patch and received approval for U.S. marketing for the intended use of hernia and other intra-abdominal soft tissue defect or deficiency repair in December, 1994.

An additional member of the *Glycar Tissue Repair Patch* family of products, the Glycar Staple Strip (K954665) was deemed substantially equivalent to the Peri-Strips™ bovine pericardial surgical staple bolsters and received approval for U.S. marketing for the intended uses of surgical stapling of lung tissue, gastric staplings, rectal and vaginal prolapse, urethral sling, reconstruction of the pelvic floor, and hernias or defects of the diaphragm, thoracic and abdominal wall in October, 1995.

The Glycar Staple Strip uses the identical material as the Glycar Tissue Repair Patch (with the addition of a synthetic suture material to assist placement of the device on the surgical stapling arm).

See in Addenda , Chart 1, Comparison Chart, under Substantial Equivalence .

b) Predicate Device Intended Use

The predicate device, the Peri-Guard™ family of glutaraldehyde-treated bovine pericardium tissue patch has been used for pericardial closures for over ten years without reported material failure; this same material has in addition been used to repair abdominal and thoracic wall defects, inguinal, paracolostomy, ventral, paraumbilical, scrotal, femoral and other hernias, urethral slings, reconstruction of pelvic floor. repair of rectal and vaginal prolapse, suture and staple bolsters, pledgets and

slings, and other soft tissue repair, reinforcement, and reconstruction without any reported patient morbidity or mortality attributed to material failures.

8. Sterilization

a) Method

The device is sterilized using exposure to formaldeyhyde and propylene oxide under enviromental control in a class 100 Clean Room enviroment. *See Outline of Sterilization Method in Addenda under Sterilization Information.*

b) Sterility Assurance Level

The *Glycar Pericardial Patches* are labeled as sterile. They are sterilized to an SAL of 10^{-6} organisms. *See in Addenda , Chart 1, Comparison Chart, under Substantial Equivalence and see Validation of Sterilization Processes under Sterilization Information.*

c) Bovine Spongiform Encephalopathy

Pericardium used for the raw material for these devices is obtained from cattle from government approved abbatoirs in Transvaal, S. Africa.

The cattle of the Republic of South Africa are certified free from B.S.E. (bovine spongiform encephalopathy)

See Figure 5 in Addenda, Certificate of B.S.E-free Status

9. Substantial Equivalence

a) Comparison with Predicate Device

The *Glycar Pericardial Patches* are substantially equivalent to the Peri-Guard™ family of glutaraldehyde-treated bovine pericardium in that they are:

i) manufactured from the same material, glutaraldehyde-treated bovine pericardium,
ii) have the same intended use,
iii) are sterilized to a minimum assurance against contamination of 10^{-6} organisms (Sterility Assurance Level, SAL = 10^{-6}), and
iv) have other performance features equal to or better than those of the predicate device.

See Comparison Chart, Chart 1, in Addenda under Substantial Equivalence and see Supporting Data

b) Technological Differences

i) Implanted Material- Bovine Pericardium

There is no difference in the implanted material used for the *Glycar Pericardial Patches* and the predicate device, Bio-Vascular Peri-Guard™. Both devices are manufactured from glutaraldehyde-treated bovine pericardium. *See Comparison Chart, Chart 1, in Addenda under Substantial Equivalence.*

ii) Sterilization Method

There is no difference in the chemical sterilization method used for Glycar Pericardial Patches versus that of the predicate device.
See Supporting Data in Addenda Under Sleeve Configuration

iii) Manufacturing Material

One difference in the manufacturing process which Glycar Inc. considers proprietary is the use of the manufacturing material, XX.

Glycar Inc. has demonstrated no adverse effects on safety or efficacy of the use of this manufacturing material, and we feel it improves safety by virtue of the properties that it confers to the material. *See Proprietary Manufacturing Material in Addenda under Confidential Information.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 1997

Dirk Frater, M.D.
Official Contact
Glycar Inc.
4504 Beverly Drive
Dallas, Texas 75205

Re: K963368 and K963967
Glycar Pericardial Patch and Glycar Vascular Patch
Regulatory Class: II
Product Code: DXZ
Dated: July 30, 1997
Received: August 4, 1997

Dear Dr. Frater:

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. **Please be advised that you may not make any claims about the effectiveness of the anticalcification treatment or durability of the device in any labeling or advertisements for this device until results of human clinical studies are submitted and found to substantiate such claims. You may, however, summarize results of animal studies performed, which should include the number and type of animal(s), location and duration of the implant, controls used, endpoints and results.**

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/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

Enclosure

510(k) Number (if known): K963967 and K963368

Device Name: Glycar Pericardial Patch and Glycar Vascular Patch

Indications For Use: The Glycar Pericardial Patch and Glycar Vascular Patch of the Glycar Tissue Repair Patch line of products are intended for pericardial closure, peripheral vascular reconstruction and repair, and cardiac and great vessel reconstruction and repair.

(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 K963967/K963368

Prescription Use X OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)