K963175

GLYCAR

510(K) SUMMARY

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3. Device Name

a) Trade Name

Glycar Tissue Repair Patch
Bio-Patch trademark pending
Uro-Sling trademark pending

b) Common Name

Biological Tissue Patch

4. F.D.A. Device Classification

Class II Device

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 Tissue Repair 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 Tissue Repair 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 shapes will be specific for product line reflecting different indications as appropriate for the use.

7. Intended Use of Product

a) Candidate Device Intended Use

The Glycar Inc., *Tissue Repair Patch* family of products have the same intended uses as the predicate device, the Bio-Vascular Inc., Peri-Guard™ family of products, which are all tissue patches 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:

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 addition to 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, the repair of 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 significant 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 Tissue Repair 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 Tissue Repair 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 uses,
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 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 *GlycarTissue Repair Patches* and the predicate device, Bio-Vascular Supple Peri-Guard™. Both devices are manufactured from gluraldehyde-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 Tissue Repair 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. *See Proprietary Manufacturing Material in Addenda under Confidential Information.*