K973552
Dec. 16, 1997

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant Name & Address:	Bio-Vascular, Inc. 2575 University Avenue St. Paul, MN 55114-1024 Fax: (612) 642-9018
Contact:	Julie Sherman Regulatory Affairs Associate Phone: (612) 603-3803
Alternate Contact:	Barb Atzenhoefer Regulatory Affairs Manager Phone: (612) 603-3795
Date Prepared:	September 18, 1997
Trade Name:	Ocu-Guard™ Orbital Implant Wrap Supple Ocu-Guard™ Orbital Implant Wrap
Common or Usual Name:	Implant, Eye Sphere (Accessory)
Device Classification Name:	Implant, Eye Sphere (Accessory)
Substantial Equivalence:	Oculo-Plastik ePTFE Sheet Covering for Ocular Implant (K934834) Peri-Guard (K821532, K833021, K842066 and K961811) Supple Peri-Guard (K921895, K923657 and K961810)

Device Description:
Ocu-Guard™ Orbital Implant Wrap and Supple Ocu-Guard™ Orbital Implant Wrap. Both products are composed of bovine pericardium, cross-linked (tanned) with glutaraldehyde.

Ocu-Guard and Supple Ocu-Guard will be available in configurations ranging from 4cmx4cm to 10cmx16cm.

Ocu-Guard and Supple Ocu-Guard will also be available as a "pre-formed" wrap. The "pre-formed" wrap will be available in configurations which will fit implant spheres ranging from 14 mm to 22 mm in size.

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Statement of Intended Use:
Ocu-Guard and Supple Ocu-Guard are intended for the wrapping of orbital implants used in enucleation procedures.

Summary/Comparison of Technological Characterisitics:
We maintain that Ocu-Guard and Supple Ocu-Guard are substantially equivalent to the predicate devices and that the extended indication for use as an orbital implant wrap does not pose new questions of safety and effectiveness. This claim is based on the following elements.

1. Configuration
The sizes of Ocu-Guard and Supple Ocu-Guard are substantially equivalent to those sold by the predicate device.

2. Extension of Indications (Labeling)
Processed bovine pericardium and the material used in the predicate device (ePTFE) have a history of being used in similar prosthetic applications. The material used in Ocu-Guard and Supple Ocu-Guard are already indicated for pericardial closure, soft tissue repair, peripheral vascular repair, dural repair and lung and bronchus resection. As summarized below and discussed earlier, we have shown that extension of these indications to include use as an orbital implant wrap does not pose new questions of safety and effectiveness.

3. Physical/Mechanical Properties
The physical and mechanical properties important for performance as an orbital implant wrap are substantially equivalent between Ocu-Guard/ Supple Ocu-Guard and the predicate device.

4. Biocompatibility
Processed bovine pericardium has a long history of biocompatibility. Peri-Guard has been marketed since 1982 with no indication of biocompatibility problems. The biocompatibility testing summarized herein is consistent with this clinical experience.

5. Rabbit Ocular Implant Studies
The rabbit ocular implant study shows that Peri-Guard and donor sclera appear to function in a similar manner, *in vivo*.

6. Canine Studies
A canine implant study shows that Supple Peri-Guard and ePTFE perform in a similar manner, *in vivo*.

7. Clinical Report
Preliminary clinical data indicates that our bovine material performs in a safe and effective manner, and in a substantially equivalent fashion to the predicate device.

8. History of Safety and Effectiveness

Peri-Guard and Supple Peri-Guard processed bovine pericardium have been used widely as an implant material for well over two decades and has been shown to be safe and effective in a variety of medical applications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 1997

Ms. Julie A. Sherman
Regulatory Affairs Associate
Bio-Vascular, Inc.
2575 University Avenue
St. Paul, MN 55114-1024

Re: K973552
Trade Name: Ocu-Guard™ and Supple Ocu-Guard™ Orbital Implant Wrap
Regulatory Class: II
Product Code: 86 MTZ
Dated: September 18, 1997
Received: September 19, 1997

Dear Ms. Sherman:

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 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) 594-4613. 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,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K973552

Device Name: Ocu-Guard™ Orbital Implant Wrap
Supple Ocu-Guard™ Orbital Implant Wrap

Indications for Use: Ocu-Guard™ and Supple Ocu-Guard™ are indicated for use as an orbital implant wrap to cover any type or shape of orbital implant used in enucleation surgery. The product is easy to handle and trim and conforms to the shape of the implant. Ocu-Guard and Supple Ocu-Guard allow for tissue ingrowth through the vascularization process and protect the surrounding orbital tissue from the surface of the orbital implant, decreasing the risk of implant exposure. Ocu-Guard and Supple Ocu-Guard also allow for muscle reattachment to facilitate motility of the implant.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Don Calogero DRL
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K973552

Prescription Use ✓ OR Over-The-Counter Use ____
Per 21 CFR 801.109

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