

K 983581

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant Name & Address: Bio-Vascular, Inc.
2575 University Avenue
St. Paul, MN 55114-1024
Fax: (651) 642-9018

Contact: Dianna L. Geck
Regulatory Affairs Associate
Phone: (651) 603-3700

Date Prepared: September 9, 1998

Common or Usual Name: Ocu-Guard Supple™ Orbital Implant Wrap (Flat & Preformed)

Device Classification Name: Eye sphere implant

Substantial Equivalence: Ocu-Guard Supple K973552

Device Description: Ocu-Guard Supple is prepared from bovine pericardium which is cross-linked with glutaraldehyde.

Statement of Intended Use: Ocu-Guard Supple is 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 Supple allows for tissue ingrowth through the vascularization process and protects the surrounding orbital tissue from the surface of the orbital implant, decreasing the risk of implant exposure. Ocu-Guard Supple also allows for muscle reattachment to facilitate motility of the implant.

Summary/Comparison of Technological Characteristics:

Cross-linked pericardium was treated with 1 molar sodium hydroxide (1M NaOH) for 60-75 minutes at 20 -25 C, rinsed with deionized (DI) water and neutralized with citrate solution, followed by a final DI water rinse. Sodium hydroxide treated and control (non-NaOH-treated) samples were subjected to shrink, suture, and thickness testing. Results showed no significant difference between the test and control samples. The test and control samples were subjected to bioburden, sterility, pH, pyrogen, and chemical residuals testing. Results showed no significant difference between the test and control samples. Samples of the NaOH-treated pericardium were also subjected to biocompatibility and animal testing. Results showed that the 1M NaOH treatment did not produce significant differences in biocompatibility or inflammation when comparing the treated versus non-treated pericardium.

Bio-Vascular believes that product subjected to 1M NaOH treatment performs in a manner substantially equivalent to the product not treated with 1M NaOH, and that the exposure to sodium hydroxide poses no additional questions of safety or effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 6 1998

Bio-Vascular, Inc.
c/o Dianna L. Geck
Regulatory Affairs Associates
2575 University Avenue
St. Paul, MN 55114-1024

Re: K983581
Trade Name: Ocu-Guard™ Supple Orbital Implant Wrap (Flat&Performed)
Regulatory Class: II
Product Code: 86 HQX
Dated: October 9, 1998
Received: October 13, 1998

Dear Ms. Geck:

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): K98 3581

Device Name: Ocu-Guard™ Supple Orbital Implant Wrap (Flat & Preformed)

Indications for Use:

Ocu-Guard Supple is 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 Supple allows for tissue ingrowth through the vascularization process and protects the surrounding orbital tissue from the surface of the orbital implant, decreasing the risk of implant exposure. Ocu-Guard Supple also allows 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)

Busan Houze Acting Branch Chief
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K983581

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