



K970851  
DEC - 9 1997

**510(k) Summary of Safety and Effectiveness  
in Accordance with SMDA of 1990**

**Lyoplant® Dura Substitute  
March 6, 1997**

Submitted by: Aesculap®, Inc.  
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**Product Name:** Lyoplant® Dura substitute  
**Common Name:** Dura substitute

**Device Description**

The Lyoplant® device is a lyophilized dura substitute of pure collagen derived from bovine pericardium. The product is supplied sterile, non-pyrogenic and packaged as single or double pieces of varying sizes.

**Intended Use**

Lyoplant is indicated as a dura mater substitute in neurological procedures for soft tissue reconstruction of damaged, impaired, or missing tissue.

**Predicate Devices**

Predicate devices are available in synthetic and organic materials (see table below).

<b>Device</b>	<b>Material Composition</b>
<b>Dura-Guard™</b> Dural Repair Patch (by Bio-Vascular, Inc.)	Glutaraldehyde cross-linked bovine pericardium.
<b>Peri-Guard®</b> Pericardium (by Bio-Vascular, Inc.)	Glutaraldehyde cross-linked bovine pericardium.
<b>Neuro-Patch</b> Dura Substitute	Polyesterurethane (PUR)
<b>Preclude</b> Dura Substitute (by W.L. Gore)	expanded polytetrafluoroethylene (ePTFE)
<b>Dura Film</b> (by Codman)	Silicone rubber sheet reinforced with Dacron® polyester.
<b>Tutoplast®</b> Dura substitute (by Biodynamics, Inc.)	Human dura composed of collagenous connective tissue.

**LYOPLANT, S&E Summary, page 2.****Technological Characteristics**

Lyoplant and its predicates have similar technological characteristics. All of these devices are available as sterile, thin flexible sheets with adequate tear resistance and handling properties, impermeability to CSF, and satisfactory biocompatibility, thus fulfilling the requirements of a dura substitute.

The technological differences between Lyoplant and the predicate devices do not raise new types of safety or effectiveness issues. The technological differences have been assessed by valid scientific and clinical methods. Physical, laboratory, animal and human clinical test methods have been performed and have proven the ability of Lyoplant to function as a dura substitute.

**Performance Data**

Performance data and test findings relative to the biocompatibility, pyrogenicity, toxicity, sterility and clinical safety have been performed and are provided in the this document. A summary of these findings are noted below.

**1. Preclinical Studies and Results**

The biocompatibility of Lyoplant has been thoroughly evaluated and addressed in numerous preclinical studies.

Through various sensitization, toxicity, and immunogenic testing, Lyoplant was found not to be a sensitizing agent under standard test procedures. The device was also found to be non-toxic and possess a weak or virtually non-reactive immunogenic potential.

Animal studies have shown the Lyoplant to be extremely well tolerated by tissues. No adverse cellular or allergic reactions were observed. The absence of giant cells demonstrates that Lyoplant is not recognized as a foreign body by the host. The implant is integrated completely into connective tissue.

**2. Clinical Studies and Results**

A clinical investigation also confirmed the excellent biocompatibility and handling properties of Lyoplant for human use. The implants showed development of connective tissue with no immunological or adverse response.

**Lyoplant, S&E Summary, page 3.****3. Manufacturing and Final Product Quality Testing**

Lyoplant is manufactured in compliance with Good Manufacturing Practice Regulations. In process and final product analytical, physical and microbiological testing assures that Lyoplant conforms to specifications prior to release.

The test data from the extensive *in vitro* and *in vivo* preclinical testing, and human clinical findings presented in the submission establish that Lyoplant is equivalent to predicate devices in its biocompatibility and its safety and effectiveness as a dura substitute.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Ms. Victoria Mackinnon  
Manager, Regulatory Affairs  
AESCULAP®  
1000 Gateway Boulevard  
South San Francisco, California 94080-7030

Re: K970851  
Trade Name: Lyoplast Dura Substitute  
Regulatory Class: II  
Product Code: GXQ  
Dated: September 29, 1997  
Received: October 1, 1997

Dear Ms. Mackinnon

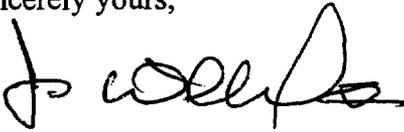
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4595. 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,



*Celia M. Witten*

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

