

05 510(k) Summary

Date: March 31st, 2014

Submitted By: Esther Carbon
Manager, Global Regulatory Labeling
RTI Surgical, Inc.
11621 Research Circle
Alachua, FL 32615
Tel: 386-418-8888
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Trade Name:

Bovine Pericardium Suturable Dural Graft, Tutopatch™ DM Graft, Tutoplast® Bovine Pericardium DM

Classification Name and Code:

Dura substitute (21 CFR 882.5910, product code GXQ)

Substantial Equivalence:

The proposed device is substantially equivalent to the predicate device Dura-Guard (K950956 and K982282) and Lyoplant (K970851) in intended use, material, design and function. The proposed device is substantially equivalent to the predicate device Dura-Matrix (K061487) in intended use, design and function. The proposed device is similar in design, function, materials and processing to reference devices Tutopatch™ bovine pericardium (K991296, K073097, K081538 and K091142) and similar to intended use, function, design and processing to reference device Tutoplast® Dura Mater (K910555).

Device Description:

The proposed device is composed of bovine pericardium processed through a proprietary tissue preservation and sterilization process which includes gamma irradiation. The proposed device is composed of collagenous connective tissue with three-dimensional intertwined fibers and can be fixed regardless of the direction of the device. Collagenous connective tissue with multidirectional fibers retains the mechanical strength and elasticity of the native tissue, while providing the basic structure to support replacement by new endogenous tissue. The proposed device in its unopened, undamaged package is sterile.

Indications for Use:

The device is indicated as a dura substitute for the repair of dura mater.

Summary of Technological Characteristics:

This proposed device is composed of non-crosslinked bovine pericardium that has been processed, terminally sterilized and stored dehydrated. The device has the same technological characteristics as the predicate device in material, design, intended use and function as listed in the table below:

Characteristic	Proposed Device	Predicate Device, Dura-Guard (K950955 and K982282)	Predicate Device, DuraMatrix (K061487)	Predicate Device, Lyoplast (K970851)	Reference Device, Tutopatch (K991296, K081538, K091142)	Reference Device, Tutodent (K073097)	Reference Device, Tutoplast processed human dura mater(K910555)
Intended Use	Dura substitute	SAME	SAME	SAME	Surgical mesh	Barrier, Animal Source, Intraoral	SAME
Material	Bovine pericardium	SAME	Bovine collagen	Collagen from bovine pericardium	SAME	SAME	Human dura
Design	Terminally sterilized sheets in various sizes	Aseptically processed sheets in various sizes	Resorbable, suturable membrane	Absorbable, suturable membrane	SAME	SAME	SAME
Function	Dura substitute	SAME	SAME	SAME	Scaffold for soft tissue repair	Scaffold for soft tissue repair	SAME
Processing	Proprietary tissue sterilization process	Apex processing	Proprietary processing	Proprietary processing	SAME	SAME	SAME
Chemical composition	Not applicable to these devices						
Energy Source	Not applicable to these devices						

Performance Data Supporting Substantial Equivalence Determination:

The proposed device is equivalent to the predicate devices in intended use, material, design, and function. The biomechanical properties of the proposed and predicate devices were evaluated in a series of *in vitro* tests and implantation in an animal model. Burst strength, uniaxial strength and suture pullout strength were substantially equivalent for the proposed and predicate devices. The table below summarizes the testing used to determine substantial equivalence of the proposed device.

Test	Results	Conclusions
Cytotoxicity – Inhibition of Cell Growth Assay	No leachable materials were released in cytotoxic concentrations from the device. The proposed device is non-cytotoxic.	Substantially equivalent
Suture Pull out (N)	The proposed device suture pull-out max load is comparable to the DuraMatrix predicate device.	Substantially equivalent
Burst Strength (N)	The proposed device burst strength is greater than the DuraMatrix predicate device.	Substantially equivalent
Shrink temperature (°C)	The shrink temperature of the proposed device is comparable to the Lyoplant predicate device.	Substantially equivalent
Max Load (N)	The maximum load at failure of the proposed device is comparable to the DuraMatrix predicate device.	Substantially equivalent

Pyrogenicity of the device was evaluated using the Limulus Amoebocyte Lysate (LAL) assay on the final sterilized device. The device did not elicit a response. All device lots will be tested to ensure the endotoxin level is <2.15 EU per device.

The functional properties of the proposed and predicate device were evaluated in a pre-clinical implantation study and the proposed device performed as well as a similar dura substitute. Clinical and gross pathology, cerebrospinal fluid leakage and the local effects of implantation were assessed and results demonstrate the proposed and predicate devices are substantially equivalent. The proposed device was increasingly resorbed. At the end time point the proposed device demonstrated moderate resorption and marked integration.

Clinical evaluation of the proposed device confirms the clinical substantial equivalence to the predicate devices. Sabatino et. al. (2014)¹ present the results of a prospective cohort study which compared the clinical outcomes from duraplasty using autologous galea-pericranium and Tutopatch (the proposed device as marketed in the European market). The study evaluated postoperative results (with a minimum follow-up of 12 months), ease of use and procedure costs. The proposed device performed adequately with no evidence of adverse health effects. Filipi et. al. (2000)² present a retrospective evaluation that summarized the outcomes for 32 patients who received Tutoplast bovine pericardium dural grafts (proposed device as marketed in ex-US countries) as part of a variety of neurosurgical procedures. The proposed device was easily sutured with standard suture material and formed a watertight seal. The proposed device provided “excellent material implantation characteristics and favorable clinical outcome”³ and is recommended as a safe and suitable material for duraplasty. Filipi et. al. concluded, “these results confirm the excellent suitability of Tutoplast bovine pericardium for dural substitution”. Results from *in vitro*, animal studies and clinical evaluation demonstrate that the proposed device is substantially equivalent to the predicate devices for use as a dura substitute.

¹ Sabatino et. al., Autologous dural substitutes: A prospective study, 116, Clin. Neuro and Neurosurgery 20-23 (2014)

^{2,3} Filipi, R., et al., Bovine pericardium for duraplasty: clinical results in 32 patients. Neurosurg Rev, 2001. 24(2-3): p. 103-7.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 31, 2014

RTI Surgical, Inc.
Ms. Esther Carbon
Manager, Global Regulatory Labeling
11621 Research Cir.
Alachua, FL 32615

Re: K132850
Trade/Device Name: Bovine Pericardium Suturable Dural Graft, Tutopatch™ DM
Graft, or Tutoplast® Bovine Pericardium DM
Regulation Number: 21 CFR 882.5910
Regulation Name: Dura Substitute
Regulatory Class: Class II
Product Code: GXQ
Dated: February 24, 2014
Received: February 26, 2014

Dear Ms. Esther Carbon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Joyce M. Whang -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K132850

Device Name

Bovine Pericardium Suturable Dural Graft
Tutoplast® Bovine Pericardium DM
Tutopatch™ DM Graft

Indications for Use (Describe)

The device is indicated as a dura substitute for the repair of dura mater.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Joyce M. Whang -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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