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

**Neuro-Patch
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Product Name: Neuro-Patch
Common Name: Dura substitute

Device Description

The Neuro-Patch device is a microporous fabric manufactured from a highly purified polyesterurethane (PUR), a synthetic material. The product is supplied sterile, non-pyrogenic and packaged as single or double pieces of varying sizes.

Intended Use

Neuro-Patch (like its predicate devices) 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).

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

Neuro-Patch, S&E Summary, page 2.

Technological Characteristics

Neuro-Patch 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 Neuro-Patch 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 Neuro-Patch 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 Neuro-Patch has been thoroughly evaluated and addressed in numerous preclinical studies.

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

Animal studies have shown the Neuro-Patch to be extremely well tolerated by tissues. The fine-fiber microstructure is characterized by intercommunicating pores with numerous openings on the surface. This facilitates rapid immigration of endogenous connective tissue cells. No adverse cellular or allergic reactions were observed. The absence of giant cells demonstrates that Neuro-Patch is not recognized as a foreign body by the host. The implant is integrated completely into connective tissue.

Neuro-Patch, S&E Summary, page 3.

2. Clinical Studies and Results

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

3. Manufacturing and Final Product Quality Testing

Neuro-Patch is manufactured in compliance with Good Manufacturing Practice Regulations. In process and final product analytical, physical and microbiological testing assures that Neuro-Patch 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 Neuro-Patch is equivalent to predicate devices in its biocompatibility and its safety and effectiveness as a dura substitute.