

AUG 14 1996

PREMARKET NOTIFICATION SUMMARY

K960656

1. **Applicant:** W. L. Gore and Associates, Inc.
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Phone: (520) 779-2771

Contact: John W. Nicholson, Associate
Date of Preparation: February 12, 1996

2. **Applicant**
Device: GORE Burr Hole Cover

Common
Name: Burr Hole Covers

Classification
Name: Burr Hole Covers

3. **Predicate Device:**

For the purposes of determining substantial equivalence, GORE cites the following as predicate devices:

- **Holter - Hausner - Burr Hole Catheter Support - K 820311**
- **Phoenix Bioengineering - Phoenix Burr Hole Button - K 913490**
- **Porex Surgical Inc. - Medpor FLEXBLOCK Implant - K 922489**

4. **Applicant Device Description:**

The GORE Burr Hole Cover device is composed of expanded polytetrafluoroethylene (ePTFE) and fluorinated ethylene propylene (FEP). The same laminate construction is used to manufacture the GORE-TEX[®] SAM Reinforced Facial Implant indicated for plastic and reconstructive surgery, and so, there are no new materials, laminate manufacturing processes or technological characteristics.

PTFE is extremely inert and has excellent chemical and thermal stability. The carbon-fluorine bond is one of the strongest bonds known among organic compounds. The highly electronegative fluorine atoms form a protective sheath enveloping the chain of carbon atoms. GORE-TEX products are characterized by solid nodes of PTFE interconnected by a latticework of PTFE fibrils. By staggering the density of the node and fibril structure, the degree and the celerity with which host tissue attachment occurs can be determined.

The FEP material is sandwiched between layers of PTFE and, because of its nonporous nature, FEP adds rigidity to the device which prevents it from sagging into the burr hole defect. The open microstructure of the ePTFE material allows for host tissue ingrowth. The Instructions for Use presented in **Attachment 3** provide basic implanting instructions.

5. Intended Use:

Like the predicate devices, the GORE Burr Hole Cover is intended to be used as a burr hole cover following cranial surgery.

6. Technological Characteristics:

The Table below presents some of the basic comparative characteristics of the applicant device and its cited predicate devices.

	Material	Origin	Intended Use	Target Population	Path to Market
GORE Burr Hole Cover	ePTFE	Synthetic	Used to cover burr holes following cranial surgery and to reattach cranial bone removed during surgery	Not Specified	<u>Class II</u> Under review
Holter - Hausner	Silicone Elastomer	Synthetic	Inserted into burr holes to provide for ventricular shunting	Not Specified	<u>Class II</u> K 820311
Phoenix Bio-Engineering	Silicone Elastomer	Synthetic	Used to plug burr holes and to secure cranial bones following cranial surgery	Not Specified	<u>Class II</u> K 913490
Porex Surgical Inc.	Porex Surgical Inc.	Synthetic	For covering burr holes drilled into the skull during surgery	Not Specified	<u>Class II</u> K 922489

For the past two decades, GORE-TEX® ePTFE Medical Products have been implanted in more than 4,000,000 clinical applications for a broad range of indications. This extensive clinical history has demonstrated that the devices possess the requisite structural, biocompatibility and mechanical characteristics to function safely and effectively. The technical, descriptive and performance data within this submission demonstrate that the applicant device is substantially equivalent to its predicate devices and that it is safe and effective for its intended use.