K964857

Appendix E--Revised January 31, 1997 FEB 18 1997

510(k) Summary
Fusion Medical Technologies, Inc.
The Patch

1. Sponsor: Fusion Medical Technologies, Inc.
1615 Plymouth Street
Mountain View, CA 94043

Contact Person: Debera Brown
Vice President, Regulatory and Clinical Affairs

Date of Summary Preparation: January 31, 1997

2. Device Name:

Trade Name: RapiSeal™ Patch
Common/Usual Name: Surgical Patch, Surgical Membrane, Surgical Mesh
Classification Name: Surgical Mesh

3. Identification of the Predicate or Legally Marketed Devices to Which Equivalence is being Claimed:

Dexon "S" Polyglycolic Acid Mesh
Davis & Geck

4. Device Description:

The Patch is a bioresorbable film containing gelatin. Each Patch is supplied sterile and non-pyrogenic in a single-use package.

5. Intended Use:

The RapiSeal Patch is intended to provide a temporary matrix during the natural tissue repair process, resulting in the additional benefit of hemostatic tamponade.

6. A Statement of How the Technological Characteristics of the Device Compare to Those of the Predicate or Legally Marketed Device(s) Cited.

The SURGICAL PATCH
Comparison to Predicate Device

	FUSION PATCH	**Dexon Mesh**
Intended Use:	Provide a temporary matrix during the natural tissue repair process	Provide temporary support during the natural tissue repair process
Indications for Use:	Hemostatic tamponade	Hemostatic tamponade
Product Form:	Thin film	Mesh
Materials:	Gelatin	Polyglycolic Acid
Absorbable:	Yes (<28 days)	Yes (60-90 days)
Method of Attachment:	Mechanical; standard electrosurgery unit	Mechanical; the mesh is sutured in place

7. Performance Data

7.1 Nonclinical Tests

7.1.1 Biocompatibility

Standard biocompatibility testing was performed according to the FDA-modified matrix recommended in FDA memorandum #G95-1 entitled: "Use of International Standard ISO-10993, Biological Evaluation of Medical Device Part-1: Evaluation and Testing".

The product passed all of the following biocompatibility tests:

Hemocompatibility
Cytotoxicity—ISO agarose overlay
Cytotoxicity—ISO elution method
Acute Systemic Toxicity
Irritation-Intracutaneous Reactivity
Genotoxicity—Ames mutagenesis
Genotoxicity—Sister chromatid exchange
Genotoxicity—Chromosomal aberration
Sensitization—Magnusson and Kligman
Implantation/Subchronic Toxicity

7.1.2 Effectiveness

Twelve pigs (6 untreated control animals and 6 Patch treated animals) underwent surgery to mimic splenic injury and bleeding. The Patch was effective in providing a means to approximate and close surgically created wounds in the spleen. In addition, the tamponade provided by the Patch resulted in complete cessation of bleeding at the wound site. Moreover, the reduction in bleeding after Patch application was significantly better than that for the untreated controls. Gross and histological examination at 7 and 28 days post-implant showed no abnormal responses to the Patch in the splenic tissue or in the abdomen, showing the Patch material to be biocompatible. No adhesions associated with Patch use were observed.

7.2 Clinical Tests

The RapiSeal Patch was used to treat air leaks in the lung in a total of 48 patients during the pre-commercial phase of the product. No Patch-related complications were reported during this clinical evaluation. In addition, the study demonstrated that the Patch was capable of successfully reducing or sealing air leaks intraoperatively.

7.3 Conclusions Drawn from Nonclinical and Clinical Testing

The conclusions drawn from the nonclinical and clinical testing were that the product is biocompatible and functional for the intended use.