K961440

MAY 31 1996

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: April 10, 1996

2. **Device Name:**

Trade Name: To be determined
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:**

Peri-Strips®
Bio-Vascular, Inc.

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 Patch reinforces the soft tissue of the lung thereby sealing or reducing air leaks that occur during pulmonary surgery.

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

Fusion Medical Technologies, Inc.
The PATCH
Comparison to Predicate Device

	The PATCH	**Peri-strip®**
Intended Use:	• Reinforce soft tissue of the lung	• Reinforce soft tissue of the lung under staple lines
Indications for Use:	• Seal or reduce air leaks in thoracic surgery	• Seal or reduce air leaks in thoracic surgery
Product Form:	Thin film	Thin film
Materials:	Gelatin	Pericardium
Absorbable:	Yes (<28 days)	Yes (2 years)
Method of Attachment:	Mechanical; standard electrosurgery unit	Mechanical; staples

7. Performance Data

7.1 Nonclinical Tests

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

7.2 Clinical Tests

Twenty six patients were enrolled in a multi-center, open label study in which the Patch was used to seal air leaks that occur during pulmonary surgery. Of the 52 leaks that were treated with the Patch, 96% were deemed to have successful closure. No product related adverse effects were noted during the study.

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.