

MAR 27 1997

510(k) Summary

Pursuant to 512(i)(3)(A) of the Food, Drug and Cosmetic Act, Apple Medical Corp. is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that information will be made available upon request of any person." Apple Medical chooses to submit a summary of the safety and effectiveness information. The summary is as follows:

Trade Name: Pneumo-Matic Insufflation Needle

Owner/Operator: Apple Medical Corporation
580 Main Street
Bolton, MA 01740
Registration # 1221923

Manufacturing Site: GEOTEC
2800 Post Road, Unit #3
Warwick, RI 02886

Device Generic Name: Spring-loaded pneumoperitoneum needle

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II, Performance Standards (21 CFR 884.1730).

Predicate Device: Dexide, Inc. Pneumo-Needle
Manufactured and Distributed by:
Dexide, Inc.
7509 Flagstone Drive
Fort Worth, TX 76181

Product Description:

The Pneumo-Matic Insufflation Needle is a sterile, disposable Veress needle which is available in a 14 gauge, 120mm or 150mm length. The devices are packaged 10 per box. The needle is equipped with a spring-loaded, round-tipped obturator. In addition, there is a "window" and visual indicator in the proximal handle which will visibly confirm penetration of the inner abdominal wall. Integral to the proximal handle is a "slide switch" which permits easy ON-OFF control of the gas flow. The most proximal end contains a male luer lock connector for secure gas line connection.

Indications for Use:

The Pneumo-Matic Insufflation Needle is intended for percutaneous insertion into the peritoneal cavity for the purpose of insufflation with carbon dioxide to establish pneumoperitoneum prior to the placement of trocars during laparoscopic procedures.

Biocompatibility:

The following biocompatibility tests were performed on the Pneumo-Matic Insufflation Needle:

1. Cytotoxicity Test
2. USP Systemic Toxicity in the Mouse
3. USP Intracutaneous Toxicity Study in the Rabbit
4. Hemolysis Test

Safety and Performance:

The following safety and performance tests were performed on the Pneumo-Matic Insufflation Needle:

1. Tip Pull Test
2. Switch operation
3. Spring Obturator Operation
4. Needle Puncture Test

Conclusion:

Based on the indications for use, technological characteristics and performance testing, the Apple Medical Pneumo-Matic Insufflation Needle has been shown to be safe and effective for its intended use.