JUL 22 1999

11.0 Summary of Safety and Effectiveness

Submitter Name and Address:	MediCor Corporation 236-B Egidi Wheeling, Illinois 60090
Contact Person: Telephone Number:	Scott B. Kerrigan 847-465-1144
Date Summary Prepared:	April 21, 1999
Proprietary Name:	The InsulScan™ Insulation Testing System
Common Name:	Insulation Tester
Classification Name:	Gynecologic laparoscope and accessories 21 CFR 884.1720 Unipolar endoscopic coagulator-cutter and accessories, 21 CFR 884.4160
Device Classification:	Class II per 21 CFR 884.1720 and 844.4160
Panel Code:	85
Procodes:	HET (884.1720) and HFG (884.4160)
Predicate Device Accessory:	LIT Insulation Testing System (K952889)

Product Design:

The InsulScan™ system is comprised of a disposable hand-held instrument probe, a control unit, a cable adapter, and a ten-foot long connection cable. The InsulScan™ system is powered by a rechargeable battery housed in the control unit. A battery recharger unit and battery charger cable are provided for recharging. The InsulScan™ probe is provided sterile, single use and may not be resterilized.

Intended Uses/Indications:

The InsulScan™ Insulation Testing System is a non-destructive, non-patient contact, high voltage insulation tester designed to test the insulation of electrosurgical instruments

Device Specifications:

Item	Specifications
Output Voltage	6,500 Volts, DC ± 1,000 Volts, DC
Supply Voltage (Battery Charger)	100 - 240 Volts, AC, 50-60 HZ, 0.80 - 0.35 Amps
Frequency	DC
Operating Duration	Continuous: 30 minutes (automatic power off)
Input Voltage	14 Volts, DC
Fuse	Non-Replaceable in Charger
Dimensions	2.5" H x 8" W x 7" D
Shipping Weight	Control Unit, 2 pounds; Charger, 13 ounces

Biological Specifications: Not required, non-patient contact.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 22 1999

Mr. Scott B. Kerrigan
Vice President, Corporate Development
MediCor Corporation
150 Fairway Drive, Suite 164
Vernon Hills, IL 60061

Re: K991424
InsulScan™ Insulation Testing System
Dated: April 21, 1999
Received: April 23, 1999
Regulatory Class: II
21 CFR §884.4160/Procode: 85 HFG

Dear Mr. Kerrigan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991424

Device Name: InsulScan™ Insulation Testing System

Indications For Use:

The InsulScan™ Insulation Testing System is a non-destructive, non-patient contact, high voltage insulation tester designed to test the insulation of electrosurgical instruments.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** _____ **Over -The-Counter Use**
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Bergman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991424