DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2006

SureTek Medical
% Mike Sammon, BME, Ph.D.
CEO/President
44 Bellwood Farms
Greenville, South Carolina 29607

Re: K052690 - Supplemental Validation Submission
Trade/Device Name: See Enclosed List
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: NUJ
Dated: January 3, 2006
Received: January 6, 2006

Dear Dr. Sammon:

The above-referenced premarket notification (510(k)) was cleared by the Office of Device Evaluation (ODE) on May 12, 2006. We have received your supplemental validation data as required for reprocessed single-use devices by the Medical Device User Fee and Modernization Act of 2002. After reviewing your supplemental validation data, we have determined the devices listed in the enclosure accompanying this letter are 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) that do not require approval of a premarket approval application (PMA). You may, therefore, market these devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (PMA) they 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 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

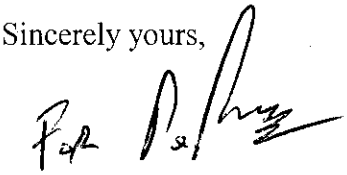
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's applicable requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in classification for your devices and thus, permits you to legally market the devices. This letter will allow you to continue marketing the devices listed in the enclosure accompanying this letter.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052690

Device Name: Suretek Reprocessed Laparoscopic Instruments

Indications For Use:

Suretek Reprocessed Laparoscopic Instruments are intended for use during general and laparoscopic surgery for cutting, grasping, dissection and electrocautery of tissue.

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K052690

Reprocessed Laparoscopic Instruments found to be substantially equivalent:

AUTOSUTURE	ENDO DISSECT 5mm	Monopolar, 33cm Length
AUTOSUTURE	ENDO SCIZ 5mm	Monopolar, 33cm Length
AUTOSUTURE	ENDO SHEARS 5mm	Monopolar, 33cm Length
CONMED	Curved Metzenbaum, 5mm	Monopolar, 32cm Length
CONMED	Curved Metzenbaum, Narrow Tip, 5mm	Monopolar, 32cm Length
CONMED	Curved Metzenbaum, Mini, 5mm	Monopolar, 32cm Length
CONMED	Maryland Dissector, 5mm	Monopolar, 32cm Length
ETHICON	Dissector, 5mm	Monopolar, 33cm Length
ETHICON	Scissors, 5mm	Monopolar, 33cm Length
GYRUS	Bipolar Cutting Forceps, 5mm	24cm Length
GYRUS	Bipolar Cutting Forceps, 5mm	33cm Length
GYRUS	Bipolar Cutting Forceps, 10mm	15cm Length
GYRUS	Bipolar Cutting Forceps, 10mm	33cm Length
GYRUS	Bipolar Needle Electrode, 5mm	33cm Length