



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: K052692 - 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: April 1, 2006
Received: April 5, 2006

Dear Dr. Sammon:

The above-referenced premarket notification (510(k)) was cleared by the Office of Device Evaluation (ODE) on May 10, 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

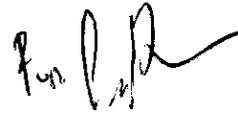
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quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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): K052692

Device Name: Suretek Reprocessed Electrosurgical Electrodes

Indications For Use:

Suretek Reprocessed Electrosurgical Electrodes are intended for use during general, arthroscopic and endoscopic surgery for RF ablation, resection and coagulation of soft tissue and hemostasis of blood vessels.

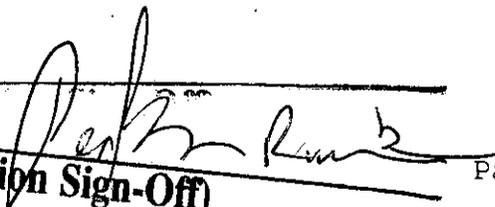
Prescription Use X
Counter Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-
Counter Use _____
(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

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Reprocessed Electrosurgical Electrodes found to be substantially equivalent:

Arthrex	OPES Ablator, Small Joint 45°	2.5mm
Arthrex	OPES Ablator, Small Joint 30°	2.5mm
Arthrex	OPES Ablator, 30°	3.0mm
Arthrex	OPES Ablator, 60°	3.0mm
Arthrex	OPES Ablator, 90°	3.0mm
Arthrex	OPES Aspirating Ablator, 60°	3.0mm
Arthrex	OPES Aspirating Ablator, 90°	3.0mm
Arthrex	OPES Ablator, 90°	4.0mm
Arthrex	OPES Aspirating Ablator, 90°	4.0mm
ArthroCare	Bevel Arthrowand, 25°	2.3mm, Black, Short 9cm
ArthroCare	Bevel Arthrowand, 35°	2.3mm, Black, Short 9cm
ArthroCare	Bevel ArthroWand, 30°	3.0mm, Black
ArthroCare	Bevel ArthroWand, 45°	3.0mm, Black
ArthroCare	Bevel Arthrowand, 60°	3.0mm, Black
ArthroCare	Dome 30 Arthrowand, 30°	2.5mm, Black
ArthroCare	Dome 60 Arthrowand, 60°	2.5mm, Black
ArthroCare	Dome 60 Arthrowand, 60°	3.0mm, Black
ArthroCare	Eliminator ArthroWand, 90°	4.5mm, Beige
ArthroCare	Eliminator ArthroWand, 90°	4.5mm, Gray w/Cable
ArthroCare	Saber ArthroWand, 30°	3.0mm, Beige
ArthroCare	Saber ArthroWand, 30°	3.0mm, Gray w/Cable
ArthroCare	Saber ArthroWand, Straight	3.5mm, Beige
ArthroCare	Covac 50 ArthroWand, 50°	3.0mm, Beige, w/Suction
ArthroCare	CoVac 50 ArthroWand, 50°	3.0mm, Gray w/Cable, w/Suction
ArthroCare	Covac 70 ArthroWand, 70°	3.0mm, Beige, w/Suction
ArthroCare	TurboVac 90 Arthrowand, 90°	3.5mm, Beige
ArthroCare	TurboVac 90 Arthrowand, 90°	3.5mm, Gray w/Cable, w/Suction
ArthroCare	TurboVac HP Arthrowand, 90°	3.5mm, High Profile, w/Suction
ArthroCare	Super TurboVac Arthrowand, 90°	3.5mm, w/Cable, w/Suction
ArthroCare	Evac T&A PlasmaWand	4.5mm, Blue, Coblator II
ArthroCare	Evac T&A PlasmaWand	4.5mm, Blue w/Cable, Coblator II
Linvatec	Lightwave Ablator, 90°	3.2mm, w/Cable
Linvatec	UltrAblator, Standard, 0°	2.5mm
Linvatec	UltrAblator, Standard, 30°	2.5mm
Linvatec	UltrAblator, Standard, 90°	2.5mm
Linvatec	UltrAblator, Standard, 0°	2.5mm
Linvatec	UltrAblator, Standard, 30°	2.5mm
Linvatec	UltrAblator, Standard, 90°	3.2mm
Linvatec	UltrAblator, Standard, 30°	3.2mm
Linvatec	UltrAblator, Standard, 90°	3.2mm
Linvatec	UltrAblator, 3-Rib, 30°	3.2mm

Linvatec	UltrAblator, 3-Rib, 90°	3.2mm
Linvatec	UltrAblator, 3-Rib, 30°	3.2mm
Mitek	VAPR End Effect Electrode	2.3mm
Mitek	VAPR End Effect Electrode	3.5mm
Mitek	VAPR End Effect Electrode	3.5mm, Angled 21°
Mitek	VAPR Side Effect Electrode	2.3mm, 8.5cm
Mitek	VAPR Side Effect Electrode	2.3mm
Mitek	VAPR Side Effect Electrode	3.5mm
Mitek	VAPR Side Effect Electrode	3.5mm, Angled 21°
Mitek	VAPR Hook Electrode 90°	3.5mm
Mitek	VAPR Suction Electrode, 90°	3.5mm