SureTek Medical 510(k) Summary K052695

Submitter	SureTek Medical 25-B Maple Creek Cir Greenville, SC 29607
Contact	Mike Sammon, Ph.D. Phone 864-299-9743
Date	9/25/05
Product	Reprocessed Arthroscopic Shavers and Burs
Classification	Code:HRX Regulation: 21 CFR 888.1100

MAY 10 2006

Predicate Devices

Manufacturer/Reprocessor	510(k)
Dyonics (Smith & Nephew)	K953695
Stryker Corp	K941333
Linvatec	K990524
Xomed (Medtronic)	K010667
Vanguard Medical Concepts	K012346
MediSISS	K012667

Device Description

Arthroscopic Shavers and Burs are powered instruments designed for cutting of soft tissue, cartilage and bone during arthroscopic/endoscopic surgeries. The stainless steel instruments consist of a hollow shaft with a distal blade or bur that rotates within an open-ended cannula with outer diameters ranging from 2 to 6 mm. Devices are designed for use only with compatible driver systems with continuous irrigation and aspiration of fluids through the inner shaft during use. Depending upon the aggressiveness required for cutting, shavers are designed with different serrated and non-serrated blades and angles, and burs have varying shapes (round, barrel, tapered) and number flutes (4 to 12). Reprocessed blades and burs have identical technological characteristics as the predicate devices, i.e. device component materials, dimensions and system compatibility are unchanged during reprocessing.

Intended Use

SureTek Arthroscopic Blades and Burs are intended for use during arthroscopic and endoscopic procedures for cutting and resection of soft tissue, cartilage and bone. Endoscopic sinus surgery is limited to small diameter instruments (2 to 3.5mm).

Testing and Standards

- Bench testing of devices following the maximum number of use and reprocessing cycles found their performance to be substantially equivalent to new, unused devices.
- SureTek cleaning process is validated to be effective for decontamination of grossly contaminated instruments under worst case operational conditions.
- Product packaging conforms to all relevant requirements of ISO 11607 *Packaging for terminally sterilized medical devices*, with performance qualifications tested according to EN868-1 and ASTM F88-00, F2906-04, D4169-04a and F1980-02.
- Product sterility and process validation conform to the relevant requirements of ISO 11135 *Medical Devices – Validation and routine control of ethylene oxide sterilization.*
- Products conform to the relevant requirements of ISO 10993 *Biological Evaluation of Medical Devices* for ethylene oxide residuals and biocompatibility of device materials.

Substantial Equivalence

Product testing and comparisons of specifications determines that SureTek Reprocessed Arthroscopic Shavers and Burs are substantially equivalent to their predicate devices with respect to device intended use and performance, as well as product packaging, labeling, sterility and safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 10 2006

SureTek Medical
c/o Mike Sammon, BME, Ph.D.
CEO/President
25-B Maple Creek Circle
Greenville, South Carolina 29607

Re: K052695
Trade/Device Name: SureTek Reprocessed Arthroscopic Blades and Burs
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:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device 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 device complies 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 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.
This letter will allow you to begin marketing your device as described in your Section 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), 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 (301) 443-6597 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

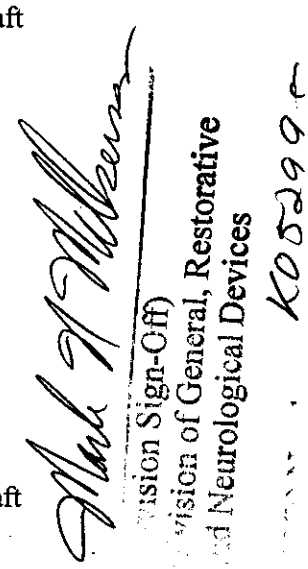
Enclosure

SureTek Medical
Reprocessed Arthroscopic Blades and Burs found to be substantially equivalent:

Dyonics	Cutter Blade	2.9mm, Beige, 7.5cm shaft
Dyonics	Cutter Blade	3.5mm, Red
Dyonics	Cutter Blade	4.5mm, Blue
Dyonics	Full Radius Blade	2.0mm, Blue, 7.5cm shaft
Dyonics	Full Radius Blade	2.9mm, Red, 7.5cm shaft
Dyonics	Full Radius Blade	3.5mm, Beige
Dyonics	Full Radius Blade	4.5mm, Yellow
Dyonics	Full Radius Blade	5.5mm, Orange
Dyonics	Incisor Blade	2.9mm, Lime Green, 7.5cm
Dyonics	Incisor Blade	3.5mm, Turquoise
Dyonics	Incisor Blade	3.5mm, Medium Grey
Dyonics	Incisor Blade	4.5mm, Lime Green
Dyonics	Incisor Blade	5.5mm, Mocha
Dyonics	Incisor Plus Blade	4.5mm, Violet
Dyonics	Incisor Plus Blade	5.5mm, Teal
Dyonics	RazorCut Blade	4.5mm, Pink
Dyonics	RazorCut Blade	3.5mm, Pink, 7.5cm shaft
Dyonics	RazorCut Blade	3.5mm, Purple
Dyonics	RazorCut Blade	5.5mm, Lt Pink
Dyonics	Synovator Blade	4.5mm, Forest Green
Dyonics	Synovator Blade	5.5mm, Melon Yellow
Dyonics	TurboTrimmer Blade	4.5mm, Powder Blue
Dyonics	TurboWhisker Blade	2.0mm, Yellow, 7.5cm shaft
Dyonics	TurboWhisker Blade	2.9mm, Green, 7.5cm shaft
Dyonics	Barrel AcromioBlaster Bur, 12 Flute	4.0mm, Sage Green
Dyonics	Barrel AcromioBlaster Bur, 12 Flute	5.5mm, Brick Red
Dyonics	Barrel Acromionizer Bur, 12 Flute	4.0mm, Mauve
Dyonics	Barrel Acromionizer Bur, 12 Flute	5.5mm, Brown
Dyonics	Barrel Abrader Bur, 4 Flute	2.9mm, Purple, 7cm shaft
Dyonics	Barrel StoneCutter Bur, 8 Flute	4.0mm, Maroon
Dyonics	Barrel StoneCutter Bur, 4 Flute	5.5mm, Olive
Dyonics	HeliCut Bur, 6 Flute	4.5mm, Slate
Dyonics	Round Abrader Bur, 4 Flute	2.9mm, Orange, 7cm shaft
Dyonics	Round Abrader Bur, 4 Flute	3.5mm, Aqua, 7cm shaft
Dyonics	Round Abrader Bur, 8 Flute	4.0mm, Aqua
Dyonics	Round Abrader Bur, 8 Flute	5.5mm, Black
Dyonics	Round Notchblaster Bur, 4 Flute	4.0mm, Lilac
Dyonics	Round Notchblaster Bur, 4 Flute	5.5mm, Peach
Linvatec	Cuda Blade, Micro Hub	2.0mm, Magenta, 7.6cm shaft
Linvatec	Cuda Blade, Micro Hub	2.9mm, Magenta, 7.6cm shaft
Linvatec	Cuda Blade, Micro Hub	3.5mm, Magenta, 7.6cm shaft
Linvatec	Cuda Blade, Large Hub	3.5mm, Magenta
Linvatec	Cuda Blade, Large Hub	4.2mm, Magenta
Linvatec	Cuda Blade, Large Hub	4.8mm, Magenta
Linvatec	Cuda Blade, Large Hub	5.5mm, Magenta
Linvatec	Dragon End Cutter, Large Hub	3.2mm, Purple
Linvatec	Dragon End Cutter, Large Hub	4.2mm, Purple
Linvatec	Dragon End Cutter, Large Hub	5.5mm, Purple
Linvatec	Full Radius Resector, Micro Hub	2.0mm, Yellow, 7.6cm shaft

SureTek Medical
Reprocessed Arthroscopic Blades and Burs found to be substantially equivalent:

Linvatec	Full Radius Resector, Micro Hub	2.9mm, Yellow, 7.6cm shaft
Linvatec	Full Radius Resector, Micro Hub	3.5mm, Yellow, 7.6cm shaft
Linvatec	Full Radius Resector, Large Hub	3.5mm, Yellow
Linvatec	Full Radius Resector, Large Hub	4.2mm, Yellow
Linvatec	Full Radius Resector, Large Hub	4.8mm, Yellow
Linvatec	Full Radius Resector, Large Hub	5.5mm, Yellow
Linvatec	Gator Blade, Micro Hub	2.0mm, Orange, 7.6cm shaft
Linvatec	Gator Blade, Micro Hub	2.9mm, Orange, 7.6cm shaft
Linvatec	Gator Blade, Micro Hub	3.5mm, Orange, 7.6cm shaft
Linvatec	Gator Blade, Large Hub	3.5mm, Orange
Linvatec	Gator Blade, Large Hub	4.2mm, Orange
Linvatec	Gator Blade, Large Hub	4.8mm, Orange
Linvatec	Gator Blade, Large Hub	5.5mm, Orange
Linvatec	Great White Blade, Large Hub	3.5mm, White
Linvatec	Great White Blade, Large Hub	4.2mm, White
Linvatec	Great White Blade, Large Hub	4.8mm, White
Linvatec	Mako Blade, Large Hub	4.2mm, Green
Linvatec	Mako Blade, Large Hub	5.5mm, Green
Linvatec	Slotted Whisker, Micro Hub	2.9mm, Red, 7.6cm shaft
Linvatec	Slotted Whisker, Large Hub	4.2mm, Red
Linvatec	Slotted Whisker, Large Hub	5.5mm, Red
Linvatec	Oval Bur, Large Hub, 6 Flute	4.0mm, Purple, High Speed
Linvatec	Oval Bur, Large Hub, 6 Flute	6.0mm, Purple, High Speed
Linvatec	Vortex Router, Micro Hub, 2 Flute	2.9mm, Green, 7.6cm shaft
Linvatec	Vortex Router, Micro Hub, 2 Flute	3.5mm, Green, 7.6cm shaft
Linvatec	Vortex Router, Large Hub, 5 Flute	4.5mm, Dk Green, High Speed
Linvatec	Vortex Router, Large Hub, 5 Flute	5.5mm, Dk Green, High Speed
Linvatec	Spherical Bur, Micro Hub, 12 Flute	2.9mm, Blue, 7.6cm shaft
Linvatec	Spherical Bur, Micro Hub, 12 Flute	3.5mm, Blue, 7.6cm shaft
Linvatec	Spherical Bur, Large Hub, 12 Flute	3.5mm, Blue, High Speed
Linvatec	Spherical Bur, Large Hub, 12 Flute	4.0mm, Blue, High Speed
Linvatec	Spherical Bur, Large Hub, 12 Flute	5.5mm, Blue, High Speed
Linvatec	Cyclone Bur, Large Hub, 6 Flute	4.5mm, Lime Green, High Speed
Linvatec	Cyclone Bur, Large Hub, 6 Flute	5.5mm, Lime Green, High Speed
Stryker	Aggressive Cutter Blade	2.0mm, Yellow, 7cm shaft
Stryker	Aggressive Cutter Blade	2.9mm, Yellow, 7cm shaft
Stryker	Aggressive Meniscus Cutter Blade	3.5mm, Yellow/Yellow
Stryker	Aggressive Meniscus Cutter Blade	4.0mm, Red/Red
Stryker	Aggressive Meniscus Cutter Blade	5.0mm, Blue/Blue
Stryker	Aggressive Plus Cutter Blade	3.5mm, Yellow/Blue
Stryker	Aggressive Plus Cutter Blade	4.0mm, Red/Blue
Stryker	Aggressive Plus Cutter Blade	5.5mm, Dark Blue/Blue
Stryker	Aggressive Plus Cutter Blade	6.0mm, Beige/Blue
Stryker	Cougar End Cutter Blade	3.5mm, Yellow/Yellow
Stryker	Cougar End Cutter Blade	4.0mm, Red/Red
Stryker	Cougar End Cutter Blade	5.5mm, Blue/Blue
Stryker	End Cutter Blade	3.5mm, Yellow/Yellow
Stryker	End Cutter Blade	4.0mm, Red/Red
Stryker	Full Radius Cutter Blade	2.0mm, Grey, 7cm shaft
Stryker	Full Radius Cutter Blade	2.9mm, Yellow, 7cm shaft



SureTek Medical
Reprocessed Arthroscopic Blades and Burs found to be substantially equivalent:

Stryker	Full Radius Cutter Blade	3.5mm, Yellow/Yellow
Stryker	Full Radius Cutter Blade	4.0mm, Red/Red
Stryker	Full Radius Cutter Blade	5.0mm, Blue/Blue
Stryker	Resector Cutter Blade	3.5mm, Yellow/Black
Stryker	Resector Cutter Blade	4.0mm, Red/Black
Stryker	Resector Cutter Blade	5.5mm, Blue/Black
Stryker	Resector Cutter Blade	6.0mm, Beige/Black
Stryker	Slotted Whisker Blade	4.0mm, Red/Red
Stryker	Tomcat Cutter Blade	4.0mm, Red/White
Stryker	Tomcat Cutter Blade	5.5mm, Blue/White
Stryker	Tomcat Cutter Blade	6.0mm, Beige/White
Stryker	Barrel Bur, 6 Flute	2.0mm, Purple, 7.5cm shaft
Stryker	Barrel Bur, 6 Flute	3.0mm, Orange, 7.5cm shaft
Stryker	Barrel Bur, 6 Flute	4.0mm, Red/Red
Stryker	Barrel Bur, 6 Flute	5.0mm, Beige/Beige
Stryker	Barrel Bur, 8 Flute	5.0mm, Blue/Beige
Stryker	Barrel Bur, 12 Flute	4.0mm, Red/Red
Stryker	Barrel Bur, 12 Flute	5.0mm, Beige/Beige
Stryker	Round Bur, 6 Flute	3.5mm, Yellow/Yellow
Stryker	Round Bur, 6 Flute	4.0mm, Red/Red
Stryker	Round Bur, 6 Flute	5.5mm, Beige/Beige
Stryker	Round Bur, 8 Flute	4.0mm, Red/Beige
Stryker	Round Bur, 8 Flute	5.0mm, Blue/Beige
Stryker	Round Bur, 12 Flute	4.0mm, Red/Red
Stryker	Round Bur, 12 Flute	5.5mm, Beige/Beige
Xomed	Inferior Turbinate Blade	2.0mm, White, 11cm shaft
Xomed	Inferior Turbinate Blade	2.9mm, White, 11cm shaft
Xomed	Serrated Blade	3.5mm, White, 11cm shaft
Xomed	Serrated Blade	4.0mm, White, 11cm shaft
Xomed	Silver Bullet Blade	2.9mm, White, 11cm shaft

Division Sign-Off)
Division of General, Restorative
and Neurological Devices
(K) Number K052695

Indications for Use

510(k) Number (if known): K052695

Device Name: SureTek Reprocessed Arthroscopic Blades and Burs

Indications for Use:

SureTek Reprocessed Arthroscopic Blades and Burs are intended for use during arthroscopic and endoscopic procedures for cutting and resection of soft tissue, cartilage and bone. Endoscopic sinus surgery is limited to small diameter instruments (2 to 3.5 mm).

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

...sion Sign-Off)
...vision of General, Restorative
...d Neurological Devices

...(k) Number K052695