JUN 0 3 2002

K012667

510(k) SUMMARY

Submitter's name: Surgical Instruments Servicing & Savings, Inc.
723 Curtis Court
Sisters, OR 97759
(541) 549-4164

Date summary prepared: August 10, 2001

Device name:

Proprietary name:	Reprocessed Arthroscopic Shapers
Common or usual name:	Various arthroscopic shapers, such as shavers, burs, and trimmers.
Classification name:	Arthroscope (888.1100). Arthroscope and accessories (87 HRX).

Legally marketed device for substantial equivalence comparison:

The predicate device for each reprocessed arthroscopic shaper is the same single use shaper as provided by the original manufacturer.

Description of the device:

The devices that are the subject of this submission are used as accessories for shaping bone and soft tissue during arthroscopic procedures. They have a variety of names, such as shavers, burs, or trimmers, are made of a variety of materials, and come in many shapes and sizes. They come from several different original equipment manufacturers as single use devices. Reprocessing includes cleaning, refurbishing, testing, packaging, and sterilization. It allows the shapers to be used several times rather than just once.

Intended use of device:

The reprocessed arthroscopic shapers are accessories intended for use in arthroscopic procedures.

Technological characteristics:

The device features of the reprocessed arthroscopic shapers and the single use shapers are very similar. The materials, dimensions, and geometry of individual shapers are identical. Both products are provided sterile. The technical characteristics, method of use, and compatibility with arthroscopic systems are also identical. The only difference is that the original products are sold for single use, while the reprocessed products can be used several times.

Testing conducted:

Each arthroscopic shaper is tested for functionality as part of the reprocessing procedures. Validation of the sterility protocol was also included in the submission.

Performance testing:

Comparative performance testing and clinical evaluations were not included as part of this 510(k).

SECTION 3 – INTENDED USE

Intended use of device:

Reprocessed arthroscopic shapers are accessories intended for use in arthroscopic procedures. Each shaper can accomplish certain kinds of cutting based on its geometry and the intended uses of the arthroscope for which it is an accessory. Some are used on bone and others on soft tissue. The shapers that are the subject of this submission are single use items that will be reprocessed, sterilized, and then reused.

Intended use of predicate device:

The predicate devices are arthroscopic shapers that are accessories to arthroscopes and are used in the procedures for which the arthroscope is cleared. Each shaper can do certain types of cutting depending on its geometry. Some are used on bone and others are used on soft tissue. The predicate devices are single use devices that are used and then discarded.

Comparison:

The general intended use for arthroscopic shapers and reprocessed arthroscopic shapers is the same. In addition, the specific uses are the same for each shaper, whether it is single use or reprocessed, because these uses are dictated by the geometry of the shaper. The single use and reprocessed shapers have the same geometry.

Labeling:

Both sets of products are generically called "Arthroscopic shapers" thereby describing their use. The Surgical Instruments Servicing & Savings, Inc. (SISS) products state clearly on the label that they have been reprocessed. Sample SISS labels can be found in Appendix III. Labeling for the predicate devices is not included in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Surgical Instruments Servicing & Savings, Inc.
c/o Mr. Robert S. McQuate
R.S. McQuate & Associates, Inc.
3636 E. Columbine Drive
Phoenix, AZ 85032

JUN 0 3 2002

Re: K012667
Trade/Device Name: Reprocessed Arthroscopic Shapers
Regulation Number: 888.1100
Regulation Name: Arthroscope and accessories
Regulatory Class: II
Product Code: HRX
Dated: March 4, 2002
Received: March 5, 2002

Dear Mr. McQuate:

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.

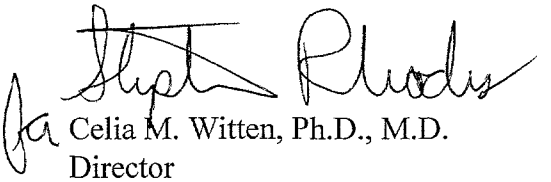
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K012667

Device name: Reprocessed Arthroscopic Shapers

Indications for Use: The reprocessed arthroscopic shapers are accessories intended for use in arthroscopic procedures.

(Please do not write below this line)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K012667

Prescription Use ✓ OR Over-The-Counter Use _____