

MAR 9 - 2005



510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter: Surgical Specialties Corporation
 Address: 100 Dennis Drive
 Reading, PA 19606
 Telephone: 610 404 1000, ext. 2231
 Contact Person: Elizabeth Lazaro
 Regulatory Affairs Specialist
 Date Prepared: February 1, 2005

Name of Device: Sharpoint Lukens® Bone Wax
 Common / Usual Classification Name: MTJ
 Bone Wax

Predicate Devices: Ethicon, Inc. Bone Wax
 CP Medical, Inc. Bone Wax

Indications For Use: The Sharpoint Lukens® Bone Wax for control of bleeding from the bone surface during surgical operations.



510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

Device Description

The Sharpoint Lukens® Bone Wax is a sterile mixture of beeswax, paraffin, and isopropyl palmitate. It has a waxy odor.

Technological Characteristics:

Bone Wax is commonly used in medical applications to control bleeding. The characteristics are the same for the proposed Sharpoint Lukens® Bone Wax as the Ethicon's Bone wax as described in this submission.



510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

Substantial Equivalence

The Sharpoint Lukens® Bone Wax is equivalent in the intended use to the predicate devices, Ethicon Bone Wax and CP Medical Bone Wax. The physical characteristics have been demonstrated to be equivalent. The components of Sharpoint Lukens® Bone Wax, Ethicon Bone Wax and CP Medical Bone wax are the same and raise no new issues of safety and efficacy.



MAR 9 - 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Elizabeth Lazaro
Regulatory Affairs Specialist
Surgical Specialties Corporation
100 Dennis Drive
Reading, Pennsylvania 19606

Re: K050292
Trade/Device Name: Sharpoint Lukens[®] Bone Wax
Regulatory Class: Unclassified
Product Code: MTJ
Dated: February 24, 2005
Received: February 25, 2005

Dear Ms. Lazaro:

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.

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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/industry/support/index.html>.

Sincerely yours.



for Miriam C. Provost, Ph.D.

Acting 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):

Device Name: Sharpoint Lukens® Bone Wax

Indications For Use:

Sharpoint Lukens® bone wax is indicated for use for control of bleeding from bone surface during surgical operations.

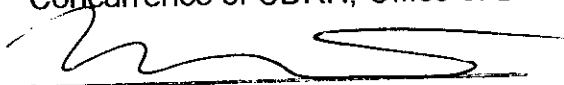
Prescription Use
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
 (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


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

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