510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

<table>
<thead>
<tr>
<th>Submitter:</th>
<th>Surgical Specialties Corporation</th>
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<tbody>
<tr>
<td>Address:</td>
<td>100 Dennis Drive</td>
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<td></td>
<td>Reading, PA 19606</td>
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<tr>
<td>Telephone:</td>
<td>610 404 1000, ext. 2231</td>
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<tr>
<td>Contact Person:</td>
<td>Elizabeth Lazaro</td>
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<td>Date Prepared:</td>
<td>February 1, 2005</td>
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<thead>
<tr>
<th>Name of Device:</th>
<th>Sharpoint Lukens® Bone Wax</th>
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<tr>
<td>Common / Usual</td>
<td>MTJ</td>
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<tr>
<td>Classification Name:</td>
<td>Bone Wax</td>
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<tr>
<th>Predicate Devices:</th>
<th>Ethicon, Inc. Bone Wax</th>
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<td>CP Medical, Inc. Bone Wax</td>
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| Indications For Use: | The Sharpoint Lukens® Bone Wax for control of bleeding from the bone surface during surgical operations. |

Sharpoint Lukens® Bone Wax
Surgical Specialties Corporation
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.
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.

Sharpoint Lukens® Bone Wax
Surgical Specialties Corporation
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.
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” (21 CFR 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,

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 _✓_ AND/OR Over-The-Counter Use ____

(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 K050292