K024372

SAFETY AND EFFECTIVENESS SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with Volume 21 of the Code of Federal Regulations, this is to serve as a Summary of Safety and Effectiveness for the proposed CP Medical Bone Wax.

Manufacturer:
CP Medical, Inc.
836 NE 24th Avenue
Portland, OR 97232
Phone: 503-232-1555
FAX: 503-230-9993

Contact Person: Sue Ridge, Technical Writer – RA/QA

Device Name:

Trade or Proprietary Name:	CP Medical Bone Wax
Common Name:	Bone Wax
Classification:	Unclassified

Date Prepared: April 15, 2003

Device Description: The proposed device is composed of a beeswax and paraffin formulation. The proposed device is manufactured in compliance with cGMP and ISO quality standards.

Predicate Devices: The proposed device is substantially equivalent to other legally marketed bone waxes, including Ethicon Bone Wax (Preamendment, Ethicon, Inc.), Lukens Bone Wax (K791495, Lukens Medical Corporation), and Auto Suture® Bone Wax (K971680, United States Surgical).

Indications: The CP Medical Bone Wax is indicated for use in the control of bleeding from bone surfaces. The device is supplied sterile and is SINGLE USE ONLY. The device may be supplied nonsterile on OEM basis only.

Intended Use: The CP Medical Bone Wax is intended to be used in the control of bleeding from bone surfaces.

Summary of Clinical and Non-Clinical Studies:
This device is proven to be reasonably safe for use as an implantable mechanical aid.

Comparison of Technological Characteristics:
The proposed device, Bone Wax, is similar, if not identical, to the predicate device in composition. Manufacture of this device, including QC testing, is in substantial compliance with current QSR and ISO quality standards.

end

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2003

Ms. Sue Ridge
Regulatory Affairs Associate
CP Medical, Inc.
836 NE 24th Avenue
Portland, Oregon 97232

Re: K024372
Trade/Device Name: CP Medical Bone Wax
Regulatory Class: Unclassified
Product Code: MTJ
Dated: April 15, 2003
Received: April 17, 2003

Dear Ms. Ridge:

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 (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) you may obtain. 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,

Miriam C. Provost

for 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

510(k) (if known): K024372

DEVICE Name: Bone Wax

Indications for Use:

The CP Medical Bone Wax is indicated for use in the control of bleeding from bone surfaces.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use _____

Miriam C. Provost

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

510(k) Number K024372