510(k) Summary – K102762

FEB 15 2011

Date: February 9, 2010

Sponsor of the 510(k)

Orthocon, Inc.
1 Bridge Street, Suite 121
Irvington, NY 10533
FDA Establishment Registration number: 3005972619
Contact: Brian Kunst, Vice President, Regulatory Affairs and Quality Assurance
914-357-2660

Device Identification:

Proprietary Name:	Orthostat Applicator
Common Name:	Bone Hemostat
Classification Name:	Bone Wax
Classification Number:	Unclassified Preamendment
Classification Panel:	General and Plastic Surgery
Product Code:	MTJ
Regulatory Class:	Unclassified Preamendment

Legally marketed device to which equivalence is claimed:

Orthostat Bone Hemostat Matrix	510(k) K043260, K091121

Intended Use / Indications

Orthostat Bone Hemostat Matrix Applicator is indicated for use in the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade. The material may be used during surgical procedures and in treating traumatic injuries

Device Description

This submission is for Orthostat packaged in a syringe type applicator containing 3.5g of Orthostat bone hemostat. This will allow convenient discharge of the putty into the surgeon's hand, onto a surgical

instrument, or directly onto bleeding bone. The tip of the applicator is tapered and made from a softer material to assist with spreading the material onto the bone.

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?[A]	X	
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X

Device comparison table

	Orthostat Applicator	Orthostat K043260, K091121
Intended use	Hemostasis on cut or traumatized bone.	Hemostasis on cut or traumatized bone.
Hemostatic Compound	Orthostat	Orthostat
Packaging	PETG Syringe	PETG Tray
Amount of Putty	3.5g	2.0g
Sterilization Method	Radiation	Radiation
SAL	10^{-6}	10^{-6}
Sterile Barrier	Foil Pouch	Foil Pouch

Summary of the non-clinical performance data

In Vitro Test Description	Results
Material Safety	Material is biocompatible and has no extractables or plasticizers.
Tip Tensile Strength	Tip attachment is acceptable and is acceptable after simulated use conditions.
Handling and Usability	The product effectively applies Orthostat during animal and human cadaver evaluation

Biocompatibility Test Description	Results
Cytotoxicity	Pass
Sensitization	Pass
Irritatiion/Intracutaneous Injection	Pass
Acute Systemic Toxicity	Pass
Pyrogen	Pass

Summary of the clinical performance data

No clinical tests were performed to determine substantial equivalence.

Conclusions drawn from the non-clinical performance data

The non-clinical tests demonstrate the Orthostat applicator is equivalent to commercially available Orthostat.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Orthocon, Inc.
% Ms. Rosemary Harry
VP, Regulatory Affairs & Quality Assurance
1 Bridge Street, Suite 121
Irvington, New York 10553

FEB 15 2011

Re: K102762
Trade/Device Name: Orthostat Bone Hemostat Matrix Applicator
Regulatory Class: Unclassified
Product Code: MTJ
Dated: February 9, 2011
Received: February 10, 2011

Dear Ms. Harry:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Indications for Use

510(k) Number: K102762

Device Name: Orthostat Bone Hemostat Matrix Applicator

Indications for Use:

Orthostat is indicated for use in the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade. The material may be used during surgical procedures and in treating traumatic injuries.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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