SEP 0 2 2005

K050411

Summary of Safety and Effectiveness

Submitter:	Zimmer Orthopaedic Surgical Products 200 West Ohio Avenue P.O. Box 10 Dover, Ohio 44622
Contact Person:	Cindy J. Dickey Regulatory Compliance Manager Telephone: (330) 364-9493 Fax: (330) 364-9490
Date:	February 14, 2005
Trade Name:	*ZIMMER A.T.S.* 3000 AUTOMATIC TOURNIQUET SYSTEM
Common Name:	Tourniquet, Pneumatic
Classification Name and Reference:	Tourniquet, Pneumatic 21 CFR § 878.5910
Predicate Devices:	Richards Pressure Sentry Tourniquet, manufactured by Richards Medical, K840206, cleared April 25, 1984. Zimmer *A.T.S.* 2000 Tourniquet System, manufactured by Zimmer Orthopaedic Surgical Products, Class 1 Exempt. Versatone D9 stethoscope, manufactured by Medasonics, preamendment device.
Device Description:	The *Zimmer A.T.S.* 3000 Automatic Tourniquet System is a non-sterile device intended to be used by qualified medical professionals to temporarily occlude blood flow in a patient's extremities during surgical procedures on those extremities. The system consists of the *A.T.S.* 3000 control unit that is coupled to the patient with the applied part

(inflatable pneumatic tourniquet cuff) via the connecting tubing. The tourniquet cuff is applied to the patient prior to the procedure beginning. The connecting tubing is attached to the inflatable tourniquet cuff and plugged into the A.T.S. 3000's connector ports.

Indications for Use:

The *A.T.S.* 3000 Automatic Tourniquet System is intended to be used by qualified medical professionals to temporarily occlude blood flow in a patient's extremities during surgical procedures on those extremities. Tourniquets have been found useful in producing a bloodless operation field in surgical procedures involving the extremities including:

Reduction of certain fractures
Kirschner wire removal
Tumor and cyst excisions
Subcutaneous fasciotomy
Nerve injuries
Tendon repair
Bone grafts
Total wrist joint replacement
Replacement of joints in the fingers
Knee joint replacements
Amputations
Replantations

Comparison to Predicate Device:

The *Zimmer A.T.S.* 3000 Automatic Tourniquet System is substantially equivalent to other legally marketed tourniquet systems, specifically the Richards Pressure Sentry Tourniquet and the Zimmer A.T.S. 2000 Tourniquet System in that the devices are similar in design, materials, and indications for use. Additionally, the LOP feature of the Zimmer *A.T.S.* 3000 Automatic Tourniquet System is substantially equivalent to the Medasonics Versatone D9 stethoscope in the determination of patient LOP.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

This device has been tested and does meet the

applicable sections of the Guidance document "Guidance for FDA Reviewers and Industry, " May 29, 1998, as well as, ANSI/AAMI/ ISO 10993-1:1997, "Biological evaluation of Medical Devices."

During the development process of the *A.T.S.* 3000, the following testing was completed:

Electrical safety testing
Hardware and Software testing
Software validation
Environmental testing
Performance testing
Risk analysis

Test protocols and summaries are included within the submission.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 0 2 2005

Ms. Cindy J. Dickey
Regulatory Compliance Manager
Zimmer Orthopaedic Surgical Products
200 West Ohio Avenue
P.O. Box 10
Dover, Ohio 44622

Re: K050411
Trade/Device Name: Zimmer A.T.S. 3000 Automatic Tourniquet System
Regulation Number: 21 CFR 878.5910
Regulation Name: Pneumatic tourniquet
Regulatory Class: I
Product Code: KCY
Dated: June 29, 2005
Received: July 8, 2005

Dear Ms. Dickey:

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" (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/dsma/dsmamain.html

Sincerely yours,

Barbara Rucker MD
for

Mark N. Melkerson
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): K050411

Device Name:

Zimmer A.T.S. 3000 Automatic Tourniquet System

Indications for Use:

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Bone grafts

Total wrist joint replacement

Replacement of joints in the fingers

Knee joint replacements

Amputations

Replantations

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) Deborah J. Mechanic for MKM

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

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510(k) Number K050411