

510(k) Summary

Attachment B

AUG 10 2011

Date Prepared: August 9, 2011

K111437

Sponsor:	Synthes Angela F. Lassandro 1301 Goshen Parkway West Chester, PA 19380 (610) 719-6854
Device Name:	Synthes RIA System
Classification:	Class II, 21 CFR §888.4540, Orthopedic manual surgical instrument Product Code: HTO & HRX
Predicate Device:	Synthes RIA System (K042899)
Device Description:	Synthes RIA System is a flexible intramedullary reaming and bone harvesting device with simultaneous irrigation and aspiration that consists of disposable tube assemblies, disposable reamer heads, disposable drive shaft seal, disposable locking clip, disposable graft filter and reusable drive shafts. The device is designed for expedited reaming of the medullary canal in preparation for internal fixation as well as the harvesting of bone and bone marrow, and as part of the treatment regimen for osteomyelitis.
Intended Use:	Synthes RIA System is intended for use in adults and adolescents (12-21 years) to clear the medullary canal of bone marrow and debris and to effectively size the medullary canal for the acceptance of an intramedullary implant or prosthesis, to harvest finely morselized autogenous bone and bone marrow for any surgical procedure requiring bone graft to facilitate fusion and/or fill bone defects, and to remove infected and necrotic bone and tissue from the medullary canal in the treatment of osteomyelitis.
Substantial Equivalence:	<p>The intent of this 510(k) is to expand and clarify the indications for use statement of the Synthes RIA system, including the use of the device for removal of infected and necrotic bone and tissue and use in the adolescent population.</p> <p>The following literature references were assessed in support of the substantial equivalence determination for the osteomyelitis addition to the indications for use statement:</p> <ul style="list-style-type: none"> • Retrospective analysis of the treatment of 18 cases of osteomyelitis in 17 patients with treatment including reaming of the intramedullary canal between 1974 and 1978 (Intramedullary Reaming in Chronic Diaphyseal Osteomyelitis: A Preliminary Report, Lidgren L, Torholm C.) • Retrospective analysis of 25 patients treated for osteomyelitis with reaming of the intramedullary canal (The value of intramedullary reaming in the treatment of chronic osteomyelitis of long bones, Ochsner PE, Gosele A, Buess P.)

- Retrospective analysis of 32 patients treated for osteomyelitis, including intramedullary reaming between 1990 and 1991 (Chronic diaphyseal osteomyelitis of long bones refractory to conventional therapy – Benefits and risks of reaming of the femoral medullary cavity, Pape H-Ch, et. al.)
- Retrospective review of two patients treated for humeral osteomyelitis, including intramedullary reaming (Management of Medullary Osteomyelitis of the Humerus, Ilyas AM, Mudgal CS)
- Case study of a 48 year old male treated for osteomyelitis with the RIA system (Use of the Reamer Irrigator Aspirator for the Treatment of 20-Year Recurrent Osteomyelitis of a Healed Femur Fracture, Bellapianta J, et. al.)
- Discussion on the use of the RIA System at a level-2 trauma center, including the use of treatment regimen of osteomyelitis (RIA: One Community's Experience, Finkemeier CG, Neiman R, Hallare D)
- Retrospective analysis of 11 patients treated between 2004 and 2005 for osteomyelitis including the use of the RIA system for debridement (Novel Technique for Medullary Canal Debridement in Tibia and Femur Osteomyelitis, Zalavras CG, Sing A, Patzakis MJ)
- Case study of a 37 year old man treated for recurrent infection, including the use of the RIA system for intramedullary reaming (RIA use in a community orthopedic trauma practice: applying technology, respecting biology, Cobbs KF)
- Several publications cited for inclusion of debridement as an integral aspect of the treatment regimen for osteomyelitis (Chronic Posttraumatic Osteomyelitis and Infected Nonunion of the Tibia: Current Management Concepts, Patzakis MJ, Zalavras CG; A Clinical Staging System for Adult Osteomyelitis, Cierny III G, Mader JT, Penninck JJ; Treatment of long bone intramedullary infection using the RIA for removal of infected tissue: Indications, method and clinical results, Zalavras CG, Sirkin M)

The following literature references were assessed in support of the substantial equivalence determination for the adolescent population addition to the indications for use statement:

- Case study of five patients discussing the placement of intramedullary nails in adolescent patients, including intramedullary reaming (Tibial Nails for Femoral Shaft Fractures in Large Adolescents with Open Femoral Physes, Mehlman CT, Bishai SK)
- Several publications cited to discuss the placement of intramedullary nails in adolescent patients, including intramedullary reaming (Intramedullary Nailing of Femoral Fractures in Children Through the Lateral Aspect of the Greater Trochanter Using a Modified Rigid Humeral Intramedullary Nail, Preliminary Results of a New Technique in 15 Children, Gordon JE, et. al.; Flexible Interlocked Nailing of Pediatric Femoral Fractures, Experience with a New Flexible Interlocking Intramedullary Nail Compared with Other Fixation Procedures, Jencikova-Celerin L, et. al.; Antegrade Intramedullary Nailing of Pediatric Femoral Fractures Using an Interlocking Pediatric Femoral Nail and a Lateral Trochanteric Entry Point, Keeler KA, et. al.)
- Two of the articles referenced above for treatment of osteomyelitis included reference to adolescent patients (Pape and Lidgren studies)
- Case study of three patients within the population range treated for osteomyelitis, including reaming of the intramedullary canal (Infected Non-union of the Tibial Shaft Treated by Kuntschner Intramedullary Reaming and Nail Fixation, A report of four cases, Lidgren L, Onnerfalt R)



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Synthes (USA) Products, LLC
% Ms. Angela F. Lassandro
1301 Goshen Parkway
West Chester, Pennsylvania 19380

AUG 10 2011

Re: K111437

Trade/Device Name: Synthes USA RIA System
Regulation Number: 21 CFR 888.4540
Regulation Name: Orthopedic manual surgical instrument
Regulatory Class: Class II
Product Code: HRX, HTO
Dated: May 03, 2011
Received: June 21, 2011

Dear Ms. Lassandro:

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

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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,



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

Enclosure

Attachment A

510(k) Number (if known): K111437

Device Name: Synthes USA RIA System

Indications for Use:

Synthes RIA System is intended for use in adults and adolescents (12-21 years) to clear the medullary canal of bone marrow and debris and to effectively size the medullary canal for the acceptance of an intramedullary implant or prosthesis, to harvest finely morselized autogenous bone and bone marrow for any surgical procedure requiring bone graft to facilitate fusion and/or fill bone defects, and to remove infected and necrotic bone and tissue from the medullary canal in the treatment of osteomyelitis.

Prescription Use X
(Per 21 CFR 801.109)

AND/OR

Over-The-Counter Use _____
(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)

Neil W. Ogden for man
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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