



**WRIGHT**  
 MEDICAL TECHNOLOGY, INC.  
 5677 AIRLINE ROAD  
 ARLINGTON, TN 38002  
 901-867-9971

## Attachment 9

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 Abbreviated 510(k) Summary
 

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## Summary

**Company:** Wright Medical Technology, Inc.

5677 Airline Road  
 Arlington, TN 38002

**Date:** March 31, 1999

**Trade Name:** PERFECTA® RS Lateralized Hip Stem

**Common Name:** Femoral Hip Stem

**Predicate Device:** Dual Offset PERFECTA® IMC Hip Stem  
 BRIDGE® Hip System

**Description/Intended Use:** The PERFECTA® RS Lateralized Hip Stem is manufactured from titanium alloy (ASTM F 136). The stem is designed to provide an increased offset during total joint replacement. The stem is available in standard lengths and features a collared and collarless version. The stem has a plasma spray coating on the posterior portion of the stem. The distal portion of the stem features a coronal slot and distal flutes. The stem is designed for press-fit applications.

This device is indicated in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

- Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
- Inflammatory degenerative joint disease such as rheumatoid arthritis;
- Correction of function deformity;
- Revision procedures where other treatments or devices have failed; and
- Treatment of nonunion, femoral neck, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

The PERFECTA® RS Lateralized Hip Stem was declared substantially equivalent to the predicate devices. Mechanical test data demonstrated that it meets the requirements cited in the FDA Guidance Documents.

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 1 1999

Ms. Lynne Witkowski  
Regulatory Affairs Associate  
Wright Medical Technology, Inc.  
5677 Airline Road  
Arlington, Tennessee 38002

Re: K991123  
Trade Name: PERFECTA® RS Lateralized Hip Stem  
Regulatory Class: II  
Product Codes: LPH and JDI  
Dated: March 31, 1999  
Received: April 2, 1999

Dear Ms. Witkowski:

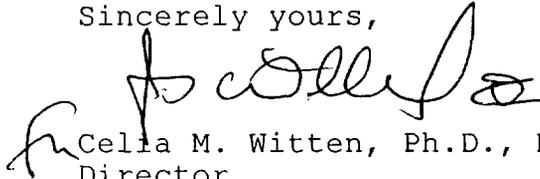
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K991123

Attachment 3

Indications for Use Statement

510(k) Number  
(if known)

Device Name

PERFECTA RS Lateralized Hip Stem

Indications for Use

This device is indicated in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

- Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
- Inflammatory degenerative joint disease such as rheumatoid arthritis;
- Correction of function deformity;
- Revision procedures where other treatments or devices have failed; and
- Treatment of nonunion, femoral neck, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  (per 21 CFR 801.109)

OR Over-The Counter Use

  
 (Division Sign-Off)  
 Division of General Restorative Devices  
 510(k) Number K991123

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