SAVE REQUEST

USER: (kml)
FOLDER: K002996 - 231 pages
COMPANY: SMITH & NEPHEW, INC. (SMITNEPH)
PRODUCT: PROSTHESIS, HIP, SEMI-CONstrained, UNCEMENTED, METAL/POLYMER, NON-POrous, CALICUM-PHOSPHATE (MEH)
SUMMARY: Product: SYNERGY HA COATED POROUS FEMORAL STEMS

DATE REQUESTED: Jan 4, 2016
DATE PRINTED: Jan 4, 2016

Note: Printed
510(k) Summary
Synergy HA Coated Porous Femoral Stems

Submitter’s name: Smith & Nephew, Inc.
Submitter’s address: 1450 Brooks Road, Memphis, TN 38116
Submitter’s telephone number: 901-399-6487
Contact person: David Henley
Date summary prepared: September 22, 2000
Trade or proprietary device name: Synergy HA Coated Porous Femoral Stems
Common or usual name: Prosthetic Hip Joint – HA Coated Porous Femoral Stem
Classification name: 21 CFR 888.3358 hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis-Class II 87LPH

Substantially Equivalent
Legally Marketed Devices

- Global Taper Tapered (Synergy) HA Hip Stem - Smith & Nephew
- Secur-Fit® HA Hip Stem – Osteonics® Corp.
- Omnifit® HA Hip Stem – Osteonics® Corp.
- Meridian® ST/PA Femoral Stem – Howmedica Corp.
- APR Porous HA Hip System – Sulzer Orthopedics, Inc.

Device Description
Synergy HA Coated Porous Femoral Stems are manufactured from titanium material (Ti-6Al-4V, ASTM F1472) and are porous coated with bead material manufactured from titanium material (Ti-6Al-4V, ASTM F67, Grade 2, with a mesh size of -45/+60. These stems are designed for use with existing Smith & Nephew cobalt chrome or ceramic modular femoral heads with a 12/14 taper.

Device Intended Use
Total hip components are indicated uncemented use only in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or non-inflammatory degenerative joint disease (NDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

The Synergy HA Coated Porous Femoral Stem is designed uncemented use only and for single use only.

Technological characteristics:
Synergy HA Coated Porous Femoral Stems are similar to the legally marketed devices listed above. All of these devices are indicated for total hip replacement, are similar in design to Synergy HA Coated Porous Femoral Stems, and have the same technological characteristics.

Performance characteristics:
Data indicate that Synergy HA Coated Porous Femoral Stems are substantially equivalent to identified legally marketed devices.
DEC 11 2000

Mr. David Henley  
Clinical/regulatory Affairs Specialist  
Smith & Nephew, Inc.  
1450 Brooks Road  
Memphis, Tennessee 38116

Re: K002996  
Trade Name: Synergy HA Coated Porous Femoral Stems  
Regulatory Class: II  
Product Code: MEH  
Dated: September 22, 2000  
Received: September 25, 2000

Dear Mr. Henley:

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 (Premarket 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 (QSR) 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 QSP 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 at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

[Signature]

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 Statement
Synergy HA Coated Porous Femoral Stems

Total hip components are indicated for un cemented use only in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or non-inflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K 00 2299 6
DEC 11 2000

Mr. David Henley
Clinical/regulatory Affairs Specialist
Smith & Nephew, Inc.
1450 Brooks Road
Memphis, Tennessee 38116

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[Signature]

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
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Synergy HA Coated Porous Femoral Stems

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Mark N. Melhorn
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K802996
From: Reviewer(s) - Name(s)  
Subject: 510(k) Number  

To: The Record - It is my recommendation that the subject 510(k) Notification:

- [ ] Refused to accept.
- [ ] Requires additional information (other than refuse to accept).
- [ ] Is substantially equivalent to marketed devices.
- [ ] NOT substantially equivalent to marketed devices.
- De Novo Classification Candidate?  [ ] YES  [ ] NO
- [ ] Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?  [ ] YES  [ ] NO
Is this device subject to the Tracking Regulation?  [ ] YES  [ ] NO
Was clinical data necessary to support the review of this 510(k)?  [ ] YES  [ ] NO
Is this a prescription device?  [ ] YES  [ ] NO
Was this 510(k) reviewed by a Third Party?  [ ] YES  [ ] NO
Special 510(k)?  [ ] YES  [ ] NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers  [ ] YES  [ ] NO

This 510(k) contains:
- [ ] Truthful and Accurate Statement requested
- [ ] Enclosed (required for originals received 3-14-95 and after)
- [ ] A 510(k) summary OR [ ] A 510(k) statement
- [ ] The required certification and summary for class III devices
- [ ] The indication for use form (required for originals received 1-1-96 and after)
- [ ] Material of Biological Origin  [ ] YES  [ ] NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):
- [ ] No Confidentiality
- [ ] Confidentiality for 90 days
- [ ] Continued Confidentiality exceeding 90 days

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

Review: [Signature] (Branch Chief)  [Signature] (Branch Code)  12/8/92
Final Review: [Signature] (Division Director)  12/8/00
Revised 8/17/99
510(k) "Substantial Equivalence" Decision-Making Process (Detailed)

New Device is Compared to Marked Device

 Does New Device Have Same Indication Statements?

 Yes

 New Device Has Same Intended Use and May Be "Substantially Equivalent"

 Does New Device Have Same Technological Characteristics, e.g., Design, Materials, etc.?

 No

 Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?

 Yes

 Performance Data Available to Assess Equivalence?

 No

 Performance Data Demonstrate Equivalence?

 No

 "Substantially Equivalent" Determination

 "Not Substantially Equivalent" Determination

 Yes

 Do the Differences Alter the Intended Therapeutic/Diagnostic/etc. Effect (In Deciding, May Consider Impact on Safety and Effectiveness)***

 New Device Has New Intended Use

 Could the New Characteristics Affect Safety or Effectiveness?

 Yes

 Do the New Characteristics Raise New Types of Safety or Effectiveness Questions?**

 Do Accepted Scientific Methods Exist for Assessing Effects of the New Characteristics?

 Yes

 Are Performance Data Available to Assess Effects of New Characteristics?****

 No

 Performance Data Required

 Yes

 Performance Data Demonstrate Equivalence?

 "Substantially Equivalent" Determination

 ** This Decision Is Normally Based on Descriptive Information Alone, But Limited Information Is Sometimes Required.

 *** Data May Be in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

 **** Additional Information Is Sometimes Required. Additional Information May Be Required, as if the Relationship Between Marketed and "Predicate" (Pre-Amendment or Reclassified Post-Amendments) Devices Is Unclear.

 Descriptive Information about New or Marketed Device Requested as Needed.
Recommendation:
This subject 510(k) notification:

☑ is substantially equivalent to the marketed devices.
☑ requires more data.
☑ requires premarket approval.

Type letter and wording suggested:
☑ “SE” Letter Attached
☑ “SW” Letter Attached
☑ “AI” Letter Attached
☑ “AI” via Telephone and/or FAX

Summary:
This Abbreviated 510(k) Includes:
1. Coversheet identifying the application as “Abbreviated 510(k): Special Controls/Conformance To Recognized Standards”;
2. Declaration of conformity with standards or guidance documents; and
3. Basic information required for all 510(k) submissions.

The sponsor has provided the necessary to fulfill the requirements for an Abbreviated 510(k). As part of an Abbreviated 510(k), the sponsor is not required to provide much of the information described in the standards or in the guidance documents. Therefore, the “SE” decision is partially/fully based on an administrative review of the conformity with consensus standards and/or guidance documents, as the new FDA regulation was intended.

Indications for Use:
Total hip components are indicated for use in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or non-inflammatory degenerative joint disease (NIDID) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis and diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; non-union; femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

Synergy HA Coated Porous Femoral Stems are not indicated for bony ingrowth (see attached FAX dated 12/5/00). It is for uncemented use and for single use only. These stems can be used with cobalt chrome or ceramic, modular femoral heads with a 12/14 taper.
Description of the Subject Device(s):
Synergy Porous Femoral Stems were previously cleared via K963509 and K991485. The only difference between this subject and the cleared predicate is the addition of an HA coating to the porous coated area on the proximal body of the Synergy porous hip stem, thus creating Synergy HA Coated Porous Femoral Stems. The proprietary HA coating utilized on Synergy HA Coated Porous Femoral Stems is identical to the HA coating used on Smith & Nephew's Hydroxyl apatite Reflection® Acetabular Shells cleared for market under K990666. The design and the manufacturing processes used for the Synergy porous coated femoral stems K963509 and K991485 has not been changed.

Materials:
HA: BioCoat, Inc. MAF-339
Porous Bead: Pure titanium, ASTM F-67
Stem: Ti6Al4V alloy, ASTM F-1472

Device dimension and geometry:
All design characteristics, including sizes, and surface finishes are identical to those predicates cleared via K963509 and K991485.

Device Testing and Results:
The HA coating is identical to the HA coating used on S&N's Hydroxyapatite Reflection® Acetabular Shells cleared via K990666.

Sterilization:
This device is intended to be provided sterile and will be sterilized by a process known to the manufacturer.

No claim of "non-pyrogenic" is made. No pyrogen testing is conducted.

Description of the packaging used to maintain sterility is enclosed. Sterile notation reflects on the sample labeling.

The product is for single use only.

Labeling:
Representative draft samples of the labeling, and package inserts are included in Exhibits 14 and 15.

Contact/Request:
12/5/2k: This reviewer called Mr. David Henly of S&N asking him the indication of this subject device specially whether or not the device is intended to promote bony ingrowth. He stated that this device system is not intended to promote bony ingrowth.

Conclusion:
This subject device is substantially equivalent to legally marketed device(s), i.e., K963509 and K991485 in terms of the stem design and dimensions. The HA coating is identical to the HA coating used on S&N's Hydroxyapatite Reflection® Acetabular Shells cleared via K990666.
Standards Data Form for Abbreviated 510(k)s

510(k) Number: K003659

Standard Organization No: ASTM
Standard Identification No: 1472, 67
CDRH Internal Reference No: 70, 411

Declaration of Conformity Elements:
Any Adaptations Applied: yes x no
Any Requirements Not Applicable: yes x no
Any Deviations Applied: yes x no
Any Differences in Device Tested and Finished Product: yes x no
Is There a Third Party or Test Lab Involved: yes no x

Comments:
The cited standard does not assure the safety and efficacy of this subject device.
Product to which compared: see review

<table>
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<tr>
<th></th>
<th>YES</th>
<th>NO</th>
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<tbody>
<tr>
<td>1. Is Product A Device</td>
<td></td>
<td>x</td>
<td>If NO = Stop</td>
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<tr>
<td>2. Is Device Subject To 510(k)?</td>
<td></td>
<td>x</td>
<td>If NO = Stop</td>
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<tr>
<td>3. Same Indication Statement?</td>
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<td>x</td>
<td>If YES = Go To 5</td>
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<tr>
<td>4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?</td>
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<td>If YES = Stop NE</td>
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<td>5. Same Technological Characteristics?</td>
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<td>If YES = Go To 7</td>
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<td>6. Could The New Characteristics Affect Safety Or Effectiveness?</td>
<td>Safety Or</td>
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<td>If YES = Go To 8</td>
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<td>7. Descriptive Characteristics Precise Enough?</td>
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<td>If NO = Go To 10</td>
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<td>8. New Types Of Safety Or Effectiveness Questions?</td>
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<td>If YES = Stop NE</td>
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<td>9. Accepted Scientific Methods Exist?</td>
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<td>If NO = Stop NE</td>
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<tr>
<td>10. Performance Data Available?</td>
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<td>If NO = Request Data</td>
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<td>11. Data Demonstrate Equivalence?</td>
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<td>Final Decision:</td>
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Note: "Yes" responses to questions 4,6,8,11, and every "No" response requires an explanation.

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performances data are needed:
11. Explain how the performance data demonstrate that the device is or is not substantially equivalent:
# Internal Administrative Form

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<tr>
<th>Question</th>
<th>YES</th>
<th>NO</th>
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<tbody>
<tr>
<td>1. Did the firm request expedited review?</td>
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<td>2. Did we grant expedited review?</td>
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<td>3. Have you verified that the Document is labeled Class III for GMP purposes?</td>
<td>X</td>
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<td>4. If, not, has POS been notified?</td>
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<td>5. Is the product a device?</td>
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<td>6. Is the device exempt from 510(k) by regulation or policy?</td>
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<td>7. Is the device subject to review by CDHR?</td>
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<td>8. Are you aware that this device has been the subject of a previous NSE decision?</td>
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<td>9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?</td>
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<td>10. Are you aware of the submitter being the subject of an integrity investigation?</td>
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<td>11. If, yes, consult the ODE Integrity Officer.</td>
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<td>12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 807632, September 10, 1991.</td>
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## Screening Checklist

2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS

<table>
<thead>
<tr>
<th>Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(4)</th>
<th>NA</th>
<th>YES</th>
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<tr>
<td>a) trade name, classification name, establishment registration number, device class</td>
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<td>b) OR a statement that the device is not yet classified</td>
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<td>c) identification of legally marketed equivalent device</td>
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<td>d) compliance with Section 514 - performance standards</td>
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<td>e) address of manufacturer</td>
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<td>f) Truthful and Accurate Statement</td>
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<td>g) Indications for Use enclosure</td>
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<td>h) Summary or Statement (FOR ALL DEVICE CLASSES)</td>
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<td>i) Class III Certification &amp; Summary (FOR ALL CLASS III DEVICES)</td>
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<td>j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals</td>
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<td>k) Proposed Labeling</td>
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<td>l) Comparison Information (similarities and differences) to nomenclaturally equivalent device</td>
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<td>m) If kit, kit certification</td>
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</table>

4. ABBREVIATED 510(K):

| a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type | NA |     |    |       |             |              |        |     |    |     |    |           |
| b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach. |     |     |    |       |             |              |        |     |    |     |    |           |
| c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard should be included | NA |     |    |       |             |              |        |     |    |     |    |           |
| d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards |     |     |    |       |             |              |        |     |    |     |    |           |

5. Additional Considerations: (may be covered by Design Controls)

| a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation |     |     |    |       |             |              |        |     |    |     |    |           |
| b) Sterilization and expiration dating information |     |     |    |       |             |              |        |     |    |     |    |           |
| c) Software validation & verification |     |     |    |       |             |              |        |     |    |     |    |           |

Passed Screening: Yes  Reviewed by: Pei Seng  Concurred by:
December 5, 2000

Dr. Pei Sung, Reviewer
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Re: K002996, Abbreviated 510(k) for Synergy HA Coated Porous Femoral Stems

Dear Dr. Sung,

(b) (4)

Sincerely,

SMITH & NEPHEW, INC.

David Henley
Clinical/Regulatory Affairs Specialist
September 26, 2000

SMITH & NEPHEW, INC.
ORTHOPAEDIC DIVISION
1450 E. BROOKS ROAD
MEMPHIS, TN 38116
ATTN: DAVID HENLEY

510(k) Number: K002996
Received: 25-SEP-2000
Product: SYNERGY HA COATED POROUS FEMORAL STEMS

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation
September 22, 2000

Office of Device Evaluation
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

RE: Abbreviated 510(k) for Synergy HA (Hydroxylapatite) Coated Porous Femoral Stems

Dear Sir or Madam:

The purpose of this letter is to notify FDA of our intent to market the Synergy HA Coated Porous Femoral Stems that are modifications of Smith & Nephew’s Global Taper “Tapered” (Synergy) Porous Hip Stems cleared for market under 510(k)’s K963509 and K991485. Smith & Nephew is submitting an Abbreviated 510(k) in accordance with requirements set forth in The New 510(k) Paradigm: Alternative Approaches to Demonstrating Substantial Equivalence in Premarket Notifications, dated March 20, 1998.

Synergy HA Coated Porous Femoral Stems conform to the following guidance documents: Draft Guidance Document for Femoral Stem Prostheses, dated August 01, 1995; Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone or Bone Cement, dated April 28, 1994; and Calcium Phosphate (Ca-P) Coating Draft Guidance for Preparation of FDA Submissions for Orthopedic and Dental Endosseous Implants, dated November 11, 1992 (reformatted 02/21/97). Ceramic heads designed for use with Synergy HA Coated Porous Femoral Stems conform to the Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems, dated January 10, 1995. Additionally, this 510(k) follows the content requirements of the Draft Guidance Document for the Preparation of Premarket Notification [510(k)] Application for Orthopedic Devices, dated July 16, 1997 and is organized in outline format for ease of locating specific content. A separate Table of Contents and List of Exhibits are provided with this submission.

We consider our intent to market these devices to be confidential commercial information, and therefore, exempt from public disclosure. To the best of my knowledge, neither I nor anyone else has disclosed through advertising or any other manner our intent to market these devices, except to employees of, or paid consultants to, our company or individuals in an advertising or law firm pursuant to commercial arrangements with appropriate safeguards for secrecy.

We believe this information fulfills the requirements for the present abbreviated 510(k) submission. Please contact us as soon as possible if clarification or additional information is required.

Sincerely
SMITH & NEPHEW, INC.

[Signature]

David Henley
Clinical/Regulatory Affairs Specialist
ABBREVIATED PREMARKET NOTIFICATION
Synergy HA Coated Porous Femoral Stems

I. ADMINISTRATIVE INFORMATION

A. The TRUTHFUL AND ACCURATE STATEMENT is provided as Exhibit 1.

B. The 510(k) SUMMARY and INDICATIONS STATEMENT are provided as Exhibit 2.

C. MANUFACTURER IDENTIFICATION

Manufacture’s Name: Smith & Nephew, Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, TN 38116

Establishment Registration Number: 1020279

Primary Contact: David Henley
Clinical/Regulatory Affairs Specialist
Ph: 901-399-6487; FAX 901-398-5146

Secondary Contact: Neal Defibaugh
Manager, Clinical/Regulatory Affairs
Ph: 901-399-5363; FAX 901-398-5146

D. DEVICE IDENTIFICATION

Proprietary Name
Synergy HA Coated Porous Femoral Stems

Common Name
Prosthetic Hip Joint – HA Coated Porous Femoral Stem

Classification Name and Reference
21 CFR 888.3358 – hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis - Class II

Device Classification for the predicate device(s)
21 CFR 888.3358 – hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis - Class II

Device Product Code and Panel Code
MEH / 87 (Orthopedics)

II. DEVICE INFORMATION

A. INTENDED USE

SynHAPor510k CONFIDENTIAL
Total hip components are indicated for use in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or non-inflammatory degenerative joint disease (NJDJ) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis and diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; non-union; femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity. **Synergy HA Coated Porous Femoral Stems** are indicated for uncemented use only and for single use only. These stems can be used with cobalt chrome or ceramic, modular femoral heads with a 12/14 taper that were cleared for market through the submissions listed in the table below.

<table>
<thead>
<tr>
<th>Description</th>
<th>Submission Number</th>
<th>Clearance Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cobalt Chrome Femoral Heads with 12/14 Taper</td>
<td>K963486</td>
<td>11-27-96</td>
</tr>
<tr>
<td>Zirconia Femoral Heads (Desmarquette) with 12/14 Taper</td>
<td>K971414</td>
<td>07-16-97</td>
</tr>
<tr>
<td>Biolox Alumina Ceramic Femoral Heads with 12/14 Taper</td>
<td>K981847</td>
<td>07-17-98</td>
</tr>
<tr>
<td>Biolox Alumina Ceramic Femoral Head, 28 mm Long with 12/14 Taper</td>
<td>K991162</td>
<td>01-28-00</td>
</tr>
</tbody>
</table>

### B. DEVICE DESCRIPTION

Components from the Global Taper Tapered Hip System (currently known as the Synergy Hip System) were cleared for market under 510(k)’s identified in the following table.

<table>
<thead>
<tr>
<th>Description</th>
<th>Submission Number</th>
<th>Clearance Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global Taper Tapered (Synergy) HA Hip Stems</td>
<td>K970337 ✓</td>
<td>02/28/97</td>
</tr>
<tr>
<td>Global Taper Tapered (Synergy) Hip System (including porous coated hip stems)</td>
<td>K963509 ✓</td>
<td>02/10/97</td>
</tr>
<tr>
<td>Synergy Porous Size 8 Hip Stem</td>
<td>K991485</td>
<td>07/12/99</td>
</tr>
<tr>
<td>Synergy Cemented Hip Stems</td>
<td>K990369</td>
<td>03/12/99</td>
</tr>
</tbody>
</table>

Components cleared under 510(k)’s K963509 and K991485 included femoral hip stems with a “rough coat” porous coating on the proximal body. **The purpose of this premarket notification submission is to add Synergy HA Coated Porous Femoral Stems to the Synergy Hip System.** A description of Synergy HA Coated Porous Femoral Stems is provided in the following sections. Representative drawings are provided as **Exhibit 3.** Summary Reports outlining Smith & Nephew’s conformance to the following guidance documents are provided in **Exhibit 4.**

• Calcium Phosphate (Ca-P) Coating Draft Guidance for Preparation of FDA Submissions for Orthopedic and Dental Endosseous Implants, dated November 11, 1992 (reformatted on 02-21-97).

Synergy HA Coated Porous Femoral Stems, that are the subject of this submission, utilize previously approved porous coated femoral stems from the Synergy Hip System cleared for market under K963509 and K991485. The only difference is the addition of a proprietary HA coating to the porous coated area on the proximal body of the Synergy porous hip stem, thus creating Synergy HA Coated Porous Femoral Stems. The proprietary HA coating utilized on Synergy HA Coated Porous Femoral Stems is identical to the HA coating used on Smith & Nephew’s Hydroxylapatite Reflection® Acetabular Shells cleared for market 05-05-99 under K990666. The design of and the manufacturing processes used for the Synergy porous coated femoral stems (K963509 and K991485) will not be changed.

Synergy HA Coated Porous Femoral Stems are straight, tapered, collarless components that utilizes identical design characteristics and geometries found in porous coated femoral stem components currently included in the Synergy Hip System (K963509). The upper, proximal body of Synergy HA Coated Porous Femoral Stems will have a “rough coat” porous coated area utilizing a ~45/+/60 mesh size, CP (commercially pure) titanium, vacuum sintered bead identical to that on the currently approved porous coated femoral hip stem components in the Synergy Hip System (K963509 and K991485). Synergy HA Coated Porous Femoral Stems will utilize the 12/14 “global taper” for modular femoral head attachment. The taper has the same design as used on components cleared under K963509 and K991485. A proprietary hydroxylapatite (HA) coating will be applied to the porous coated area on the Synergy HA Coated Porous Femoral Stems. All other design characteristics and surface finishes are identical to those utilized on previously cleared Synergy porous coated femoral stems (K963509 and K991485).

Synergy HA Coated Porous Femoral Stem will be made available in sizes 9 through 20 in both standard and high offset versions. Except for sizes 19 and 20, this is the same size range that is presently available with Synergy Porous Femoral Stems (i.e. size 8 cleared under K991485 and sizes 9 through 18 cleared under K963509). As previously mentioned, the size 8 Synergy HA Coated Porous Femoral Stem will be available in a standard offset version only.

Fatigue Strength Analysis & Static Shear Strength of the Surface/Substrate Interface

For the purposes of this submission, references are made to fatigue strength analyses performed on the worst case stem sizes and an analysis of the static shear strength of the surface/substrate interface as presented in Synergy Hip System 510(k) submissions K963509 and K991485. Several Smith & Nephew Orthopaedic Test Reports, a Technical Memo, and hand calculations reporting these analyses from K963509 and K991485 are summarized below and copies are provided in Exhibits 5 and 6.

OR-96-84 - Fatigue Strength Prediction of a New Tapered Hip Stem, August 1996 - Originally provided as a part of Exhibit 15 in K963509, this test report evaluated the worst
case, size 9 high offset, Tapered (Synergy) Hip Stem using finite element analysis (FEA) and found it exhibited a fatigue strength. This strength was found greater than that for the clinically proven size 10.5 DePuy AML® hip stem (see Exhibit 5).

Hand Calculations - Originally provided as Exhibit 5 in K991485, hand calculation results (see Exhibit 6).

HA Coating Design Validation

As previously mentioned, the proprietary HA coating that will be utilized on Synergy HA Coated Porous Femoral Stems is identical to the HA coating used on Smith & Nephew’s Hydroxylapatite Reflection® Acetabular Shells cleared for market 05-05-99 under K990666. In addition to previously submitted test reports concerning fatigue strength determinations for the Synergy Porous Hip Stems included in K963509 and K991485, these tests were conducted in accordance with the following FDA guidance documents:

- Calcium Phosphate (Ca-P) Coating Draft Guidance for Preparation of FDA Submissions for Orthopedic and Dental Endosseous Implants, dated November 11, 1992 (reformatted effective 02-21-97)
- Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement, dated April 28, 1996. Summary reports citing Smith & Nephew’s efforts to conform to the requirements of these guidance documents are provided in Exhibit 4.
Stem Use with Ceramic Femoral Heads

*Synergy HA Coated Porous Femoral Stems* are designed for use with Smith & Nephew cobalt chrome, Biofox Alumina Ceramic, and Zirconia Ceramic femoral heads that utilize the 12/14 global taper (see table of premarket submissions provided under section A, Intended Use, on page 2 of this document). Summary reports of testing for the Biofox Alumina Ceramic Femoral Heads and the Zirconia Femoral Heads are provided as a part of Exhibit 4.

Information on the femoral heads contained in Exhibit 4 is the same as that submitted in Exhibit 12 of K983834, Echelon Hip Stems and Exhibit 9 of K990369, Synergy Cemented Hip Stems. Additional information, such as 510(k) clearance letters and \[b(4)\], is provided as Exhibits 7 and 8, respectively. Additional information regarding the Biofox Alumina Ceramic Femoral Heads is provided as Exhibit 9. A technical memo provided as Exhibit 10 was previously submitted in support of K991162. It is provided as Exhibit 10.

C. MATERIAL INFORMATION

*Synergy HA Coated Porous Femoral Stems* are manufactured from Ti-6Al-4V, titanium alloy material conforming to the requirements of ASTM F1472-93. This is the same material used in the manufacture of Synergy HA stems (K970337) and Porous hip stems (K963509 and K991485). The requirements for the porous coating are the same as that cleared for Synergy Porous hip stems (K963509 and K991485).

Porous coated stems conform to the *Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone or Bone Cement*, dated April 28, 1994 (see summary report provided as a part of Exhibit 4). *Synergy HA Coated Porous Hip Stems* are subsequently coated with a proprietary HA coating applied by a plasma spray technique. The HA coating will be applied by \[b(4)\] (vendor) to Smith & Nephew, Inc. Additional information relevant to the HA coating can be found in Exhibit 4.

The Biofox Alumina Ceramic Femoral Head is manufactured from (ASTM F603 and ISO 6474). Additional information about this material is available in the masterfile for our supplier. Information is provided as Exhibit 11.
The Zirconia Ceramic Femoral Head is manufactured [REDACTED] (b)(4). This is provided as Exhibit 12.

D. STERILIZATION INFORMATION

Synergy HA Coated Porous Femoral Stems will be sterilized by [REDACTED] (b)(4). Sterilization information is provided as Exhibit 13. If HA porous coated femoral stems are inadvertently contaminated, users are advised to return the unsoiled prosthesis to Smith & Nephew, Inc. for resterilization. Porous coated implants are not to be resterilized. They require specialized cleaning procedures.

E. LABELING

Important medical information contained in a package insert is provided as Exhibit 14. A sample of the general package labeling is provided as Exhibit 15. All carton labels have the same general design and follow the same format. Unfortunately, advertising literature is not available at this time.

F. SUBSTANTIAL EQUIVALENCE INFORMATION

Synergy HA Coated Porous Femoral Stems are very similar to HA Global Taper Tapered (Synergy) Hip Stems. They are also similar to the competitive devices listed below and in Table 1 provided as Exhibit 17. While Synergy HA Coated Porous Femoral Stems are not identical to all of the predicates, any differences that may exist do not significantly affect device safety and effectiveness. Therefore, it is concluded that Synergy HA Coated Porous Femoral Stems are substantially equivalent to the devices listed below. See Exhibit 19 for marketing brochures and 510(k)-clearance information on substantially equivalent devices.

- Global Taper Tapered (Synergy) HA Hip Stems (K970337) – Smith & Nephew, Inc.
- Secur-Fit™ HA Hip System (K990203) – Osteonics® Corp.
- Omnifit® HA Hip Stem (K982032) – Osteonics® Corp.
- Meridian® ST/PA Femoral Stem (K971206) – Howmedica
- APR Porous HA Hip Stem (K973124) – Sulzer Orthopedics, Inc.

Synergy HA Coated Porous Femoral Stems are very similar to the Global Taper Tapered (Synergy) HA Hip Stems cleared for market under K970337. Components from the previously approved Synergy HA hip stems have similar physical geometries. Both Synergy stem varieties are made from identical titanium material, offer uncemented fixation, and have the same indications for use. The only difference between the two stem varieties is that Synergy HA Coated Porous Femoral Stems have a proprietary HA coating [REDACTED].
Synergy HA Coated Porous Femoral Stems are similar to the Osteonics® Secur-Fit™ hip stems in that components from both systems are made from titanium material, have HA coating on the proximal surface, offer uncemented fixation, and have similar indications for use.

Synergy HA Coated Porous Femoral Stems are similar to the Osteonics® Ominfit® HA Hip Stems in that components from both systems are made from titanium material, have HA coating on the proximal surface, offer uncemented fixation, and have similar indications for use.

Synergy HA Coated Porous Femoral Stems are similar to the Howmedica Meridian® ST/PA Femoral Stems in that components from both systems have HA coating applied to a porous substrate on the proximal surface, offer uncemented fixation, and have similar indications for use.

Synergy HA Coated Porous Femoral Stems are similar to the Sulzer Orthopedics, Inc. APR Porous HA Hip Stems in that components from both systems are made from titanium material, have HA coating on the proximal surface, offer uncemented fixation, and have similar indications for use.

III. DECLARATION of CONFORMITY with CONSENSUS STANDARDS

A. The Synergy HA Coated Porous Femoral Stems to be introduced conform in all respects with the current requirements of ASTM F1472-93, Standard Specification for Wrought Ti-6Al-4V Alloy for Surgical Implant Applications. The porous bead material (sintered to the stem) conforms to ASTM F67-95, Standard Specification for Unalloyed Titanium for Surgical Implant Applications:

Requirement
1. Manufactured from titanium material conforming to the chemical composition limits and mechanical requirements of specification ASTM F1472-93. The porous bead material conforms to the requirements of ASTM F67-95.

B. The hip stems to be introduced have been evaluated per strength requirements established in ISO 7206 (where applicable). These stems were previously evaluated by finite element analysis (FEA) and hand calculations generated per loading conditions established in ISO 7206-4 (see Smith & Nephew Orthopaedic test reports, Technical Memos, and hand calculation spreadsheets provided as a part of Exhibits 5 and 6). When evaluated according to information contained in the ISO 7206 standard, the provisions of ISO 7206, relative to actual mechanical testing, are not applicable.

C. These devices are certified to comply with the voluntary standards as contained in ASTM F1472-93, ASTM F67-95, and the requirements of ISO 7206, as specified and so stipulated above, unless and where specifically so indicated to be at variance with the standard specification, in which case information, data and analysis, or justification for non-
applicability, are provided to fully describe the variance and its impact on the device and to justify said variance.

David Henley
Clinical/Regulatory Affairs Specialist

September 22, 2000
Date
# Table of Contents

Synergy HA Coated Porous Femoral Stems

## SECTION

### I. ADMINISTRATIVE INFORMATION

A. TRUTHFUL and ACCURATE STATEMENT

B. 510(K) SUMMARY & INDICATIONS STATEMENT

C. MANUFACTURER IDENTIFICATION
   - Manufacturer's Name
   - Establishment Registration Number
   - Primary and Secondary Contact

D. DEVICE IDENTIFICATION
   - Proprietary Name
   - Common Name
   - Classification Name and Reference
   - Device Classification for the Predicate Device
   - Device Product Code and Panel Code

### II. DEVICE INFORMATION

A. INTENDED USE

B. DEVICE DESCRIPTION

C. MATERIAL INFORMATION

D. STERILIZATION INFORMATION

E. LABELING

F. SUBSTANTIAL EQUIVALENCE INFORMATION

G. DECLARATION of CONFORMITY with CONSENSUS STANDARDS

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<tr>
<th>SECTION</th>
<th>PAGE #</th>
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<tbody>
<tr>
<td>I. ADMINISTRATIVE INFORMATION</td>
<td>Exhibit 1</td>
</tr>
<tr>
<td>II. DEVICE INFORMATION</td>
<td>1 - 2</td>
</tr>
</tbody>
</table>

SynHAPorTOC

CONFIDENTIAL
List of Exhibits
Synergy HA Coated Porous Femoral Stems

Exhibit 1
Truthful and Accurate Statement

Exhibit 2
510(k) Summary and Indications Statement

Exhibit 3
Drawings

Exhibit 4
Summary Reports:
3) Calicum Phosphate (Ca-P) Coating Draft Guidance for Preparation of FDA Submissions for Orthopaedic and Dental Endosseous Implants, November 11, 1992 (reformatted 02/21/97).

Exhibit 5

Exhibit 6
1) Technical Memo: TM116901/1, Finite Element Analysis of Porous Coated Synergy Size 8 Hip Stem With +4 and -3 Head Offset, April 26, 1999.
2) Hand Calculation Spreadsheets – Synergy Porous Size 8 Hip Stem

Exhibit 7
Femoral Head 510(k) Clearance Letters for(b)(4) and Zirconia Ceramic 12/14 Global Taper (GT) Femoral Heads

Exhibit 8
Engineering Drawings for(b)(4) and Zirconia Ceramic Femoral Heads

Exhibit 9
Technical Memo: TM181801, Finite Element Analysis of 28mm Medium Offset vs. 32mm Long Offse(b)(4) -H96CCAC, July 1, 1998.

Exhibit 10
Exhibit 11  Letter of Access for *(b) (4)* Masterfile
Exhibit 12  Letter of Access for *(b) (4)* Masterfile
Exhibit 13  Sterilization Information
Exhibit 14  Sample Package Insert
Exhibit 15  Sample Package Label
Exhibit 16  Letter of Access for *(b) (4)* Masterfile
Exhibit 17  Table 1 – Substantial Equivalence Information
Exhibit 18  Synergy HA Coated Porous Femoral Stem Calcium Phosphate Coating Characterization Form
Exhibit 19  Marketing and 510(k) Clearance Information on Substantially Equivalent Devices
I certify that, in my capacity as a Clinical and Regulatory Affairs Specialist for the Orthopaedic Division of Smith & Nephew, Inc., I believe to the best of my knowledge, that all data and information submitted in this 510(k) premarket notification are truthful and accurate and that no material fact has been omitted.

Signature

[Signature]

David Henley
Clinical and Regulatory Affairs Specialist

September 22, 2000
Date
510(k) Summary
Synergy HA Coated Porous Femoral Stems

Submitter’s name: Smith & Nephew, Inc.
Submitter’s address: 1450 Brooks Road, Memphis, TN 38116
Submitter’s telephone number: 901-399-6487
Contact person: David Henley
Date summary prepared: September 22, 2000
Trade or proprietary device name: Synergy HA Coated Porous Femoral Stems
Common or usual name: Prosthetic Hip Joint – HA Coated Porous Femoral Stem
Classification name: 21 CFR 888.3358 hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis-Class II 87LPH

Substantially Equivalent Legally Marketed Devices
- Global Taper Tapered (Synergy) HA Hip Stem - Smith & Nephew
- Secur-Fit® HA Hip Stem – Osteonics® Corp.
- Omnifit® HA Hip Stem – Osteonics® Corp.
- Meridian® ST/PA Femoral Stem – Howmedica Corp.
- APR Porous HA Hip System – Sulzer Orthopedics, Inc.

Device Description
Synergy HA Coated Porous Femoral Stems are manufactured from titanium material (Ti-6Al-4V, ASTM F1472) and are porous coated with bead material manufactured from titanium material (Ti-6Al-4V, ASTM F67, Grade 2, with a mesh size of −45/+60). These stems are designed for use with existing Smith & Nephew cobalt chrome or ceramic modular femoral heads with a 12/14 taper.

Device Intended Use
Total hip components are indicated uncemented use only in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or non-inflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

The Synergy HA Coated Porous Femoral Stem is designed uncemented use only and for single use only.

Technological characteristics:
Synergy HA Coated Porous Femoral Stems are similar to the legally marketed devices listed above. All of these devices are indicated for total hip replacement, are similar in design to Synergy HA Coated Porous Femoral Stems, and have the same technological characteristics.

Performance characteristics:
Data indicate that Synergy HA Coated Porous Femoral Stems are substantially equivalent to identified legally marketed devices.
Indications Statement
Synergy HA Coated Porous Femoral Stems

Total hip components are indicated for uncemented use only in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or non-inflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.
SUMMARY REPORT

Guidance Document for Femoral Stem Prostheses

The following information is prepared per requirements set forth in the Guidance Document for Femoral Stem Prostheses, dated August 1, 1995. Sections provided below are dedicated to the Synergy HA Coated Porous Femoral Stem.

Synergy HA Coated Porous Femoral Stem

Material and Design Description
Synergy HA Coated Porous Femoral Stems are line additions to the Global Taper Tapered (Synergy) Hip System cleared for market under 510(k)'s K963509, K970337, and K991485. Features of the Synergy HA Coated Porous Femoral Stem design are described in section II, B, Device Description as contained in the Abbreviated Premarket Notification. The Synergy HA Coated Porous Femoral Stem is designed to accept a variety of femoral heads as stated in section II, A, Intended Use. The subject stems are made from titanium (Ti-6Al-4V) material (ASTM F1472) as stated in section II, C, Material Information. Drawings of the femoral component are provided in Exhibit 3.

Evaluation of Surface Treatments
(b)(4)

Information describing stem surface treatments is provided in section II, B, Device Description as contained in the Abbreviated Premarket Notification and summary reports provided in Exhibit 4.

Evaluation of Ceramic Ball Hip Systems
Information describing the evaluation of the Synergy HA Coated Porous Femoral Stem per the requirements outlined in the Guidance Document for Preparation of Premarket Notifications for Ceramic Ball Hip Systems, dated January 05, 1995, is provided as a part of Exhibit 4.

Fatigue Analysis Using FEA and Hand Calculations

(b)(4)

Fatigue analysis demonstrated by the
SUMMARY REPORT

Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone or Bone Cement

The following information is prepared per requirements set forth in the Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone or Bone Cement, dated April 28, 1994. As this document relates to the Global Taper Tapered (Synergy) Hip System (Synergy Porous Hip Stems) and, more specifically, Synergy HA Coated Porous Femoral Stems, engineering drawings for both stem types have identical specifications for porous coating requirements. Thus, the specifications provided below describe conformance to the guidance document request for limited information for beaded, sintered titanium coatings on a titanium substrate.

Synergy HA Coated Porous Femoral Stem

The head material used in porous coating the Synergy HA Coated Porous Femoral Stem conforms to the recommendations of the guidance document.

The porous coating information cited above is also contained in Smith & Nephew Orthopaedics test report OR-95-144 and was originally provided in Exhibit 15 of 510(k) K963509 and is included in this submission as a part of Exhibit 5.
SUMMARY REPORT

Calcium Phosphate (Ca-P) Coating Draft Guidance for Preparation of FDA Submissions for Orthopedic and Dental Endosseous Implants

The following information is prepared per requirements set forth in FDA guidance *Calcium Phosphate (Ca-P) Coating Draft Guidance for Preparation of FDA Submissions for Orthopedic and Dental Endosseous Implants*, dated November 11, 1992 (reformatted 2/21/97).

Information on Coating Application and Characterization, as described in sections III and IV of the subject FDA guidance document, is provided in detail in *(b)(4)* Device Master File, MAF-339. A letter authorizing FDA access to *(b)(4)* Device Master File in support of regulatory submissions by Smith & Nephew, Inc. is provided as Exhibit 16. This information is also provided in summary form as outlined in section VI of the subject FDA guidance document. A summary document entitled Calcium Phosphate Coating Characterization Form, formatted as required by section VI of the guidance document, is provided in this submission as Exhibit 18.
SUMMARY OF TESTING
Memorandum

To: David Henley
From: Jeff Sprague
Subject: Technical Memo
cc: P. Frederick, M. Harbaugh, A. Salehi, D. Ryan

Date: April 26, 1999

b(4) Trade Secret Process - Technical Report
Appendix B: Calculations
Dear Ms. Kuhne:

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 and the following limitation that the package insert must reflect that the Biolox Alumina Ceramic Femoral Heads are to be used only with cobalt-chrome and Ti6Al4V alloy Smith & Nephew hip stems with the 12/14 taper trunnions, and that the 28 mm long sized femoral head is not for use with cobalt-chrome tapers.

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 (Premarket 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 immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and 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,

[Signature]

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
Indications Statement
Biolox Alumina Ceramic Femoral Head

Total hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma; inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion; femoral neck fracture and trochanteric fractures of the proximal femur with heads involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

Prescription Use  
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number  
K 08647

CONFIDENTIAL
Jan 28 2000

Mr. David Henley
Clinical/Regulatory Affairs Specialist
Smith & Nephew, Inc.
1450 Brooks Road
Memphis, Tennessee 38116

Re: K991162
Trade Name: Biolox Alumina Ceramic Femoral Head, 28 mm Long, 12/14 Taper
Regulatory Class: II
Product Code: LZO
Dated: November 3, 1999
Received: November 4, 1999

Dear Mr. Henley:

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 control 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 (Premarket 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 at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Indications Statement
28 mm. Long Biolox Alumina Ceramic Femoral Head

Total hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage free period; nonunion; femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip, and correction of deformity.

(Division Sign-Off)
Division of General Restorative Devices 510(k) Number K99 1162

Prescription Use X
(Per 21 CFR 801.109)
Ms. JoAnn Kuhne  
Manager, Regulatory and Clinical Affairs  
Smith and Nephew, Inc.  
1450 Brooks Road  
Memphis, Tennessee 38116

Re: K971414  
Zirconia Ceramic 12/14 Global  
Taper (GT) Femoral Heads  
Regulatory Class: II  
Product Code: L20  
Dated: April 15, 1997  
Received: April 16, 1997

Dear Ms. Kuhne:

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 and the following limitation that the package insert must reflect that the Zirconia Ceramic 12/14 Global Taper (GT) Femoral Heads are to be used only with cobalt-chrome and Ti6Al4V alloy hip stems with the 5°43' Morse taper trunnions.

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 (Premarket 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 immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and 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,

[Signature]

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
Exhibit 2

Indications for Use:

INTENDED USE:

The Zirconia femoral head components are to be used with other total hip components as part of a total hip arthroplasty. The components are indicated for cemented and uncemented use for individuals undergoing primary and revision surgery where other treatments or devices have failed for rehabilitating hips damaged as a result of trauma, or non-inflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Indications also include inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; old, remote osteomyelitis with an extended drainage-free period, in which case, the patient should be warned of an above normal danger of infection postoperatively; treatments of nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with heads involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip; and correction of deformity.

The devices are for single use. These head devices may be used with stems that are available with cementless or cement fixation. These heads have not been submitted to the FDA for identical or different intended uses.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off) Division of General Restorative Devices
510(k) Number 971412
Biolox Alumina Ceramic
Femoral Heads

Engineering Drawings
Memorandum

To: Janet Green

From: Mary Anthony

Date: July 6, 1998

cc: J. Shea, M. Harbaugh, A. Salehi, D. Todd, File

Subject: [Redacted] Long Offset Biolo[Redacted]

[Redacted]
APPENDIX A

28 M and 32 L Alumina Biolox Head Prints
Memorandum

To: Jeff Shea

From: Abraham Salehi and Reginald Thomas

Subject: Technical Memo - [Redacted]

Date: November 3, 1999

[Redacted]
STERILITY INFORMATION

Gamma Irradiation

Source / Type of Sterilization: Cobalt 60 / Gamma irradiation

Sterility Assurance Level: $10^{-6}$

Type of Cycle: Overkill

Dosage: 25 Kilo grays minimum

Validation: Validation is accomplished by following the procedures set forth by the Association for the Advancement of Medical Instrumentation (AAMI) Guideline for Gamma Radiation Sterilization, ANSI / AAMI ST32-1991.

Description of Packaging: The packaging is PETG thermoformed tray with Tyvek lid heat sealed to the tray and placed inside a second PETG tray with Tyvek lid. The trays are inserted into a paper board carton that is shrink wrapped.

Pyrogen Statement: These products are not labeled as “non-pyrogenic”. Applications of orthopedic implants are such that routine pyrogen testing is not required.

Primary Contract Sterilizer: Sterigenics International
1700 North Airport Road
West Memphis, AR 72301

SteriGenics International
3001 Wichita Court
Fort Worth, TX 76140
IMPORTANT MEDICAL INFORMATION
Warnings and Precautions
Total Hip System

IMPORTANT NOTE
Total hip replacement arthroplasty has become a successful procedure for relieving pain and restoring motion in patients who are disabled from hip arthropathy. The goals of total hip replacement are to decrease pain, increase function, and increase mobility.

MATERIALS
Femoral components are cobalt chromium alloy, titanium 6Al-4V alloy or stainless steel. Femoral heads are cobalt chromium alloy, zirconia ceramic, alumina ceramic or stainless steel. Acetabular liners are ultra-high molecular weight polyethylene or alumina ceramic. Acetabular components are ultra-high molecular weight polyethylene. Acetabular shells are titanium 6Al-4V alloy. The component material is provided on the outside carton label.

NOTE: Ceramic/ceramic implants are not available in the USA.

Some of the alloys needed to produce orthopedic implants contain some metallic components that may be carcinogenic in tissue cultures or intact organism under very unique circumstances. Questions have been raised in the scientific literature as to whether or not these alloys may be carcinogenic in implant recipients. Studies conducted to evaluate this issue have not identified conclusive evidence of such phenomenon, in spite of the millions of implants in use.

DESCRIPTION OF SYSTEM
The Total Hip System consists of femoral components, proximal pads, taper sleeves, distal sleeves, acetabular components, fixation screws and pegs, hole covers, centralizers, and femoral heads. Components may be grit blasted, porous coated, hydroxylapatite (HA) coated, or HA porous coated. All implantable devices are designed for single use only.

Femoral Components
Femoral components are available in a variety of sizes. Porous coated components are coated for biological ingrowth. Proximally and distally modular femoral components accept proximal pads and distal sleeves, respectively. Non-porous femoral components can feature PMMA centralizers that help produce a uniform thickness of cement.

Femoral components are available with a Small, Large (14/16), or 12/14 global taper.

Small taper femoral components mate and lock directly with a 22 mm metal or ceramic head. The Small taper also mates with a taper sleeve which, in turn, mates with either metal or ceramic heads (26, 28, or 32 mm), bipolar or unipolar components.

Large taper femoral components mate and lock with either metal heads (26, 28, or 32 mm), ceramic heads (28 or 32 mm), bipolars or unipolar components.
Femoral components with a 12/14 taper mate and lock with either metal heads (22, 26, 28, or 32 mm), ceramic heads (22, 26, 28, or 32 mm), bipolar or unipolar components.

Small, Large, and 12/14 taper femoral component tapers are machined to mate and lock with ceramic heads, thus preventing rotation of the ceramic head on the stem, which would cause wear of the stem taper.

**Taper Sleeves**
A taper sleeve is required to be impacted on the Small taper femoral component prior to impacting a femoral head size 26, 28, or 32 mm. A taper sleeve is required to attach a unipolar head. Unipolar taper sleeves are available in Small, Large, and 12/14 tapers. Never place more than one taper sleeve on a femoral component.

**Femoral Heads**
Cobalt chromium (22, 26, 28, and 32 mm) and ceramic (22, 26, 28, and 32 mm) heads are available in multiple neck lengths for proper anatomic and musculature fit. Heads are highly polished for reduced friction and wear. The following zirconia ceramic heads are available for use only with Small and Large taper femoral components:

<table>
<thead>
<tr>
<th>Zirconia Ceramic</th>
<th>Head Diameter</th>
<th>Neck Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>42-7815</td>
<td>32 mm</td>
<td>Standard</td>
</tr>
<tr>
<td>42-7816</td>
<td>32 mm</td>
<td>Long</td>
</tr>
<tr>
<td>42-7817</td>
<td>32 mm</td>
<td>X-Long</td>
</tr>
<tr>
<td>42-7818</td>
<td>28 mm</td>
<td>Standard</td>
</tr>
<tr>
<td>42-7819</td>
<td>28 mm</td>
<td>Long</td>
</tr>
<tr>
<td>42-7820</td>
<td>28 mm</td>
<td>X-Long</td>
</tr>
</tbody>
</table>

Note: 32 mm heads with a -3 mm neck length are not available for use with the Small taper stems.

In addition to the components listed above, the following components are available for use only with Small taper femoral components:

<table>
<thead>
<tr>
<th>Zirconia Ceramic</th>
<th>Head Diameter</th>
<th>Neck Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>7132-0002</td>
<td>22 mm</td>
<td>Long</td>
</tr>
<tr>
<td>7132-0006</td>
<td>22 mm</td>
<td>X-Long</td>
</tr>
</tbody>
</table>

Note: 22 mm Zirconia Ceramic Heads used with Small taper femoral components are not available in the U.S.A.

The following zirconia ceramic heads are available for use only with 12/14 taper femoral components:
<table>
<thead>
<tr>
<th>Zirconia Ceramic</th>
<th>Head Diameter</th>
<th>Neck Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>7132-0028</td>
<td>28 mm</td>
<td>0 mm</td>
</tr>
<tr>
<td>7132-0428</td>
<td>28 mm</td>
<td>+ 4 mm</td>
</tr>
<tr>
<td>7132-0828</td>
<td>28 mm</td>
<td>+ 8 mm</td>
</tr>
<tr>
<td>7132-0026</td>
<td>26 mm</td>
<td>0 mm</td>
</tr>
<tr>
<td>7132-0426</td>
<td>26 mm</td>
<td>+ 4 mm</td>
</tr>
<tr>
<td>7132-0826</td>
<td>26 mm</td>
<td>+ 8 mm</td>
</tr>
<tr>
<td>7132-0422</td>
<td>22 mm</td>
<td>+ 4 mm</td>
</tr>
<tr>
<td>7132-0822</td>
<td>22 mm</td>
<td>+ 8 mm</td>
</tr>
</tbody>
</table>

The following alumina ceramic heads are available for use only with 12/14 taper femoral components:

<table>
<thead>
<tr>
<th>Alumina Ceramic</th>
<th>Head Diameter</th>
<th>Neck Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>7133-2800</td>
<td>28 mm</td>
<td>0 mm</td>
</tr>
<tr>
<td>7133-2804</td>
<td>28 mm</td>
<td>+ 4 mm</td>
</tr>
<tr>
<td>7133-2808</td>
<td>28 mm</td>
<td>+ 8 mm</td>
</tr>
<tr>
<td>7133-3200</td>
<td>32 mm</td>
<td>0 mm</td>
</tr>
<tr>
<td>7133-3204</td>
<td>32 mm</td>
<td>+ 4 mm</td>
</tr>
<tr>
<td>7133-3208</td>
<td>32 mm</td>
<td>+ 8 mm</td>
</tr>
</tbody>
</table>

**Acetabular Components**

Acetabular components can be one piece all polyethylene, two-piece component consisting of a titanium shell and a polyethylene liner or a titanium shell and an alumina ceramic liner. Please see Warnings and Precautions for specific information on screws, pegs and hole covers use. Acetabular reinforcement and reconstruction rings are used with all polyethylene acetabular component. Note: The metal shell and ceramic liner in the Ceramic/Ceramic Acetabular System are not available in the U.S.A.

Femoral components and femoral heads are designed for use with any Smith & Nephew polyethylene acetabular component or polyethylene-lined, metal-backed acetabular component having an appropriately-sized inside diameter.

**INDICATIONS, CONTRAINDICATIONS, AND ADVERSE EFFECTS**

Hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; old, remote osteomyelitis with an extended drainage-free period, in which case, the
patient should be warned of an above normal danger of infection postoperatively; treatments of nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip; and correction of deformity.

Acetabular reinforcement and reconstruction rings are intended to be used in primary and revision surgeries where the acetabulum has the deficiencies of the acetabular roof, anterior or posterior pillar, medial wall deficiency, and/or protrusion as a result of the indications listed previously. Some of the diagnoses listed above and below may also increase the chance of complications and reduce the chance of a satisfactory result.

**Contraindications**

1. Conditions that would eliminate or tend to eliminate adequate implant support or prevent the use of an appropriately-sized implant, e.g.:
   a. Blood supply limitations;
   b. Insufficient quantity or quality of bone support, e.g., osteoporosis, or metabolic disorders which may impair bone formation, and osteomalacia; and
   c. Infections or other conditions which lead to increased bone resorption.
2. Mental or neurological conditions which tend to impair the patient’s ability or willingness to restrict activities.
3. Physical conditions or activities which tend to place extreme loads on implants, e.g., Charcot joints, muscle deficiencies, multiple joint disabilities, etc.
4. Skeletal immaturity.
5. The zirconia ceramic head is contraindicated for use with any other product than an UHMW polyethylene cup or a metal backed UHMW polyethylene cup.
6. The alumina ceramic liner is contraindicated for use with any product other than the metal shell with the correlating inner taper geometry and the appropriate sized alumina ceramic head. The alumina ceramic liner should only be used with the alumina ceramic head.

Contraindications may be relative or absolute and must be carefully weighted against the patient’s entire evaluation and the prognosis for possible alternative procedures such as non-operative treatment, arthrodesis, femoral osteotomy, pelvic osteotomy, resection arthroplasty, hemiarthroplasty and others.

Conditions presenting increased risk of failure include: osteoporosis, metabolic disorders which may impair bone formation, and osteomalacia.

**Possible Adverse Effects**

1. Wear of the polyethylene and ceramic articulating surfaces of acetabular components may occur. Higher rates of wear may be initiated by the presence of particles of cement, metal, or other debris which can develop during or as a result of the surgical procedure and cause abrasion of the articulating surfaces. Higher rates of wear may shorten the useful life of the prosthesis, and lead to early revision surgery to replace the worn prosthetic components.
2. With all joint replacements, asymptomatic, localized, progressive bone resorption (osteolysis) may occur around the prosthetic components as a consequence of foreign-body reaction to
particulate wear debris. Particles are generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion, and fatigue. Secondarily, particles may also be generated by third-body particles lodged in the polyethylene or ceramic articular surfaces. Osteolysis can lead to future complications necessitating the removal or replacement of prosthetic components.

3. Loosening, bending, cracking, or fracture of implant components may result from failure to observe the Warnings and Precautions below. Fracture of the implant can occur as a result of trauma, strenuous activity, improper alignment, or duration of service.

4. Dislocations, subluxation, decreased range of motion, or lengthening or shortening of the femur caused by improper neck selection, positioning, looseness of acetabular or femoral components, extraneous bone, penetration of the femoral prosthesis through the shaft of the femur, fracture of the acetabulum, intrapelvic protrusion of acetabular component, femoral impingement, periprosthetic calcification, and/or excessive reaming.

5. Fracture of the pelvis or femur: post-operative pelvic fractures are usually stress fractures. Femoral fractures are often caused by defects in the femoral cortex due to misdirected reaming, etc. Intraoperative fractures are usually associated with old congenital deformity, improper stem selection, improper broaching, and/or severe osteoporosis.

6. Infection, both acute post-operative wound infection and late deep wound sepsis.

7. Neuropathies; femoral, sciatic, peroneal nerve, and lateral femoral cutaneous neuropathies have been reported. Temporary or permanent nerve damage resulting in pain or numbness of the affected limb.

8. Wound hematoma, thromboembolic disease including venous thrombosis, pulmonary embolus, or myocardial infarction.

9. Myositis ossificans, especially in males with hypertrophic arthritis, limited pre-operative range of motion and/or previous myositis. Also, periarticular calcification with or without impediment to joint mobility can cause decreased range of motion.

10. Trochanteric nonunion usually associated with early weight bearing and/or improper fixation of the trochanter, when a transtrochanteric surgical approach is used.

11. Although rare, metal sensitivity reactions and/or allergic reactions to foreign materials have been reported in patients following joint replacement.

12. Damage to blood vessels.

13. Traumatic arthrosis of the knee from intraoperative positioning of the extremity.


15. Aggravated problems of the affected limb or contralateral extremity caused by leg length discrepancy, excess femoral medialization, or muscle deficiency.

16. Failure of the porous coating/substrate interface or hydroxylapatite coating/porous coating bonding may result in bead separation delamination.

17. Stem migration or subsidence has occurred in conjunction with compaction grafting procedures usually resulting from insufficient graft material or improper cement techniques. Varus stem alignment may also be responsible.

**WARNINGS AND PRECAUTIONS**

The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should be warned that the device does not replace normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that it has a finite expected service life and may need to be replaced in the future. Do not mix components from
different manufacturers. Additional Warnings and Precautions may be included in component literature.

Preoperative
1. Use extreme care in handling and storage of implant components. Cutting, bending, or scratching the surface of components can significantly reduce the strength, fatigue resistance, and/or wear characteristics of the implant system. These, in turn, may induce internal stresses that are not obvious to the eye and may lead to fracture of the component. Implants and instruments should be protected from corrosive environments such as salt air during storage. Do not allow the porous surfaces to come in contact with cloth or other fiber-releasing materials.
2. Allergies and other reactions to device materials, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively.
3. Fixation and expected longevity of components expected to be left in place at revision surgery should be thoroughly assessed.
4. Surgical technique information is available upon request. The surgeon should be familiar with the technique. Refer to medical or manufacturer literature for specific product information.
5. Intraoperative fracture or breaking of instruments can occur. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Instruments should be examined for wear, or damage, prior to surgery.
6. Do not cold water quench ceramic components and never sterilize ceramic heads while fixed on the stem taper. (See sterilization section, below.)
7. Select components such that the Zirconia ceramic head always articulates with a UHMW polyethylene cup or a metal backed UHMW polyethylene cup. Zirconia ceramic should never articulate against metal because severe wear of the metal will occur.
8. Select only Smith & Nephew femoral components that indicate their use with ceramic heads. This is important because the taper on the stem is machined to tightly mate and lock with the ceramic head thus preventing rotation of the ceramic head on the stem. Also, an improperly dimensioned taper could result in fracture of the ceramic head.
9. The zirconia ceramic head is composed of a new ceramic material with limited clinical history. Although mechanical testing demonstrates that when used with a polyethylene acetabular component, the yttria stabilized zirconia ball produces a relatively low amount of particulates, the total amount of particulate remains undetermined. Because of the limited clinical and preclinical experience, the biological effect of these particulates can not be predicted.
10. Alumina ceramic should never articulate against metal because severe wear could occur.

Intraoperative
1. The general principles of patient selection and sound surgical judgment apply. The correct selection of the implant is extremely important. The appropriate type and size should be selected for patients with consideration of anatomical and biomechanical factors such as patient age and activity levels, weight, bone and muscle conditions, any prior surgery and anticipated future surgeries, etc. Generally, the largest cross-section component which will allow adequate bone support to be maintained is preferred. Failure to use the optimum-sized
component may result in loosening, bending, cracking, or fracture of the component and/or bone.

2. Correct selection of the neck length and cup, and stem positioning, are important. Muscle looseness and/or malpositioning of components may result in loosening, subluxation, dislocation, and/or fracture of components. Increased neck length and varus positioning will increase stresses which must be borne by the stem. The component should be firmly seated with the component insertion instruments.

3. Care should be taken not to scratch, bend (with the exception of the Reconstruction Rings) or cut implant components during surgery for the reasons stated in Number One of the "Pre-Operative" section of "Warnings and Precautions."

4. A +12 mm or +16 mm femoral head should not be used with any Small taper stems.

5. Distal sleeves should not be used to bridge cortical defects that lie within 25 mm of the tip of the base stem.

6. Matrix Small taper stem sizes 8S - 10L must have a minimum neck length of +8 mm when used with a bipolar component, and Small taper stem sizes 12S - 16L must have a minimum neck length of +4 mm when used with a bipolar component.

7. Modular heads and femoral components should be from the same manufacturer to prevent mismatch of tapers.

8. Clean and dry stem taper prior to impacting the femoral head or taper sleeve. The modular femoral head component must be firmly seated on the femoral component to prevent disassociation.

9. Take care, when positioning and drilling screw and peg holes, to avoid penetration of the inner cortex of the pelvis, penetration of the sciatic notch, or damage to vital neurovascular structures. Perforation of the pelvis with screws that are too long can rupture blood vessels causing the patient to hemorrhage. Do not place a screw in the center hole of the acetabular prosthesis. Placement of drills and screws in the anterior or medial portions of the prosthesis is associated with a high risk of potentially fatal vascular injury. Bone screws must be completely seated in the holes of the shell to allow proper locking for the acetabular component liner. If the tapered pegs need to be removed from the shell after impaction of the pegs, do not reuse the pegs or the peg shell holes. Use new pegs and different shell holes, or a new shell if necessary.

10. USE ONLY REFLECTION® TITANIUM BONE SCREWS, UNIVERSAL CANCELLOUS BONE SCREWS, TAPERED PEGS, AND HOLE COVERS with the Reflection Acetabular Component and USE ONLY OPTI-FIX® TITANIUM BONE SCREWS AND UNIVERSAL CANCELLOUS BONE SCREWS with the Opti-Fix Acetabular Component. The Reflection InterFit and the Reflection For Screws Only (FSO) shells accept Universal Cancellous, Reflection screws, and tapered screw-hole covers, not pegs. Tapered pegs can only be used with Reflection V Shells. The threaded center hole in Reflection Shells only accepts the threaded hole cover, not screws or pegs. The InterFit threaded hole cover is only for use with Reflection Interfit. The Reflection threaded hole cover can be used with both Reflection and InterFit shells. Refer to product literature for proper adjunctive fixation and hole cover usage.

11. Prior to seating modular components, surgical debris including tissue must be cleaned from the surfaces. Debris, including bone cement, may inhibit the component locking mechanism. If the shell is to be cemented in place, remove extraneous cement with a plastic sculps tool to ensure proper locking of the liner. During liner insertion, make sure soft tissue does not
interfere with the shell/liner interface. Chilling the liner reduces the impaction force required
to seat the liner. Modular components must be assembled securely to prevent disassociation.
Debris inhibits the proper fit and locking of modular components which may lead to early
failure of the procedure. Failure to properly seat the acetabular liner into the shell can lead to
disassociation of the liner from the shell.

12. Avoid repeated assembly and disassembly of the modular components which could
compromise the critical locking action of the locking mechanism.

13. Care is to be taken to assure complete support of all parts of the device embedded in bone
cement to prevent stress concentration which may lead to failure of the procedure. During
curing of the cement, care should be taken to prevent movement of the implant components.

14. If components are to be left in place at revision surgery, they should first be thoroughly
checked for signs of looseness, etc. and replaced if necessary. The head/neck component
should be changed only when clinically necessary.

15. Once removed from the patient, implants previously implanted should never be reused, since
internal stresses which are not visible may lead to early bending or fracture of these
components.

16. With the congenitally dislocated hip, special care should be taken to prevent sciatic nerve
palsy. Also, note that the femoral canal is often very small and straight and may require an
extra-small straight femoral prosthesis; however, a regular-sized prosthesis should be used
when possible. Note that the true acetabulum is rudimentary and shallow. A false
acetabulum should not ordinarily be utilized as a cup placement site for anatomical and
biomechanical reasons.

17. With rheumatoid arthritis, especially for those patients on steroids, bone may be extremely
osteoporotic. Care should be taken to prevent excessive penetration of the acetabular floor or
fracture of the medial acetabular wall, femur, or greater trochanter.

18. Revision procedures for previous arthroplasty, Girdlestone, etc., are technically demanding
and difficult to exercise. Common errors include misplacement of the incision, inadequate
exposure or mobilization of the femur, inadequate removal of ectopic bone, or improper
positioning of components. Postoperative instability as well as excessive blood loss can
result. In summary, increased operative time, blood loss, increased incidence of pulmonary
embolus and wound hematoma can be expected with revision procedures.

19. Prior to closure, the surgical site should be thoroughly cleaned of cement, bone chips, ectopic
bone, etc. Ectopic bone and/or bone spurs may lead to dislocation or painful or restricted
motion. Range of motion should be thoroughly checked for early contact or instability.

20. When using a ceramic liner and metal shell, proper shell and liner alignment and positioning
are critical to implant performance. If the ceramic liner and shell are not fully seated or are
aligned incorrectly after final impaction, it will be necessary to revise the shell and liner with
new components. An improper impaction will damage the shell and liner taper which can
increase the chance of subsequent liner fracture or other component failure. Refer to the
surgical technique for specific information on shell assembly and the implantation method.

21. Proper positioning of the components is important to minimize impingement which could
lead to early failure, premature wear, and/or dislocation.

Postoperative

1. Postoperative directions and warnings to patients by physicians, and patient care, are
extremely important. Gradual weight bearing is begun after surgery in ordinary total hip
arthroplasty. However, with trochanter osteotomy or certain complex cases, weight-bearing status should be individualized with the non or partial weight-bearing period extended.

2. Patients should be warned against unassisted activity, particularly use of toilet facilities and other activities requiring excessive motion of the hip.

3. Use extreme care in patient handling. Support should be provided to the operative leg when moving the patient. While placing the patient on bedpans, changing dressings, and clothing, and similar activities, precautions should be taken to avoid placing excessive load on the operative part of the body.

4. Postoperative therapy should be structured to regain muscle strength around the hip and a gradual increase of activities.

5. Periodic x-rays are recommended for close comparison with immediate postoperative conditions to detect long-term evidence of changes in position, loosening, bending and/or cracking of components or bone loss. With evidence of these conditions, patients should be closely observed, the possibilities of further deterioration evaluated, and the benefits of early revision considered.

6. Prophylactic antibiotics should be recommended to the patient similar to those suggested by the American Heart Association for conditions or situations that may result in bacteremia.

PACKAGING AND LABELING
Components should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact.

STERILIZATION/RESTERILIZATION
Most implants are supplied sterile and have been packaged in protective trays. The method of sterilization is noted on the package label. All radiation sterilized components have been exposed to a minimum of 25 kiloGrays of gamma radiation. If not specifically labeled sterile, the implants and instruments are supplied non-sterile and must be sterilized prior to use. Inspect packages for punctures or other damage prior to surgery.

Metal Components
Nonporous or non-HA coated metal components may be initially sterilized or resterilized, if necessary, by steam autoclaving in appropriate protective wrapping, after removal of all original packaging and labeling. Protect the devices, particularly mating surfaces, from contact with metal or other hard objects which could damage the product. The following process parameters are recommended for these devices:

- Prevacuum Cycle: 4 pulses (Maximum = 26.0 psig (2.8 bars) & Minimum = 10.0 inHg (339 millibars)) with a minimum dwell time of 4 minutes at 270°F to 275°F (132°C to 135°C), followed by a 1 minute purge and at least 15 minutes of vacuum drying at 10 inHg (339 millibars) minimum.
- Gravity Cycle: 270°F to 275°F (132°C to 135°C) with a minimum dwell time at temperature of 10 minutes, followed by a 1 minute purge and at least 15 minutes of vacuum drying at 10 inHg (339 millibars) minimum.

Smith & Nephew does not recommend the use of low temperature gravity cycles or flash sterilization on implants.
Do not resterilize femoral prostheses with ceramic heads seated on the stem.

If porous coated or HA coated implants are inadvertently contaminated, return the unsoiled prosthesis to Smith & Nephew for resterilization. DO NOT RESTERILIZE porous coated or HA coated implants. The porous coating requires special cleaning procedures.

**Plastic Components**
Plastic components may be resterilized by ethylene oxide gas. The following parameters are recommended as starting points for cycle validation by the health care facility:

<table>
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<th>Sterilant</th>
<th>Temp. (°F/°C)</th>
<th>Humidity (%)</th>
<th>Maximum Pressure</th>
<th>Concentration (mg/l)</th>
<th>Exposure Time (min)</th>
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<tr>
<td>100% EtO</td>
<td>131°F (55°C)</td>
<td>40-80% (70% Target)</td>
<td>10 PSI (689 millibars)</td>
<td>725</td>
<td>60-180</td>
</tr>
</tbody>
</table>

Suggested initial starting point for aeration validation is 12 hours at 120°F (49°C) with power aeration. Consult aerator manufacturer for more specific instructions.

**Ceramic Components**
Do not resterilize ceramic femoral heads or liners.

**INFORMATION**
For further information, please contact Customer Service at (800) 238-7538 for calls within the continental USA and (901) 396-2121 for all international calls.

**Authorized EC Representative:** Smith & Nephew Orthopaedics GmbH, Tuttlingen, Germany.

**Caution:** Federal Law (USA) restricts this device to sale by or on the order of a physician.

Matrix, Opti-Fix and Reflection are trademarks of Smith & Nephew, Inc.
STERILE

Contents sterile unless package is damaged or opened.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Sample Labels
## General Product Carton Label

<table>
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<tr>
<th>Code</th>
<th>Description</th>
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<tr>
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<td>Size 8, Synergy HA Coated</td>
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<tr>
<td></td>
<td>Porous Femoral Component</td>
</tr>
<tr>
<td>Qty. (1)</td>
<td>Standard Offset, 12/14 Taper</td>
</tr>
<tr>
<td>STEM</td>
<td>Ti-6Al-4V</td>
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<tr>
<td>Sterile</td>
<td></td>
</tr>
</tbody>
</table>

For Use With Smith & Nephew  
12/14 Femoral Heads Only

Pkg. Date: mm/yy  Lot No. XXXXXXXX  
Smith & Nephew, Inc., Orthopaedic Division, Memphis, TN USA

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
12/14 taper allows use of 22, 26, 28 and 32 mm metal or ceramic femoral heads. Proven taper design minimizes potential for corrosion and debris generation.

Polished circumferential neck increases range of motion while reducing the risk of dislocation.

10 sizes in 1 mm increments cover a wide range of patient variability. All sizes come in standard and high offset.

Rounded medial curvature matches proximal femoral geometry.

Roughened forged titanium surface allows bone ingrowth and promotes stability.

Threaded in-line driving platform provides version control.

Proximal geometry coated with 50 µm high shear strength hydroxyapatite coating.

3/4 mm flutes increase rotational stability.

3° proximal to distal taper increases implant stability. 3 point contact (posterior-anterior-posterior) provides immediate rigid fixation.

Polished distal bullet tip reduces end of stem cortical bone contact.

Smith+Nephew
Leadership in Worldwide Healthcare

Smith & Nephew, Inc. • 1450 Brooks Road • Memphis, TN 38116 U.S.A.
(901) 396-2121 • For information: 1-800-821-5700 • For orders and order inquiries: 1-800-238-7538

Synergy is a trademark of Smith & Nephew, Inc. ©1999 Smith & Nephew, Inc.
Secur-Fit™ HA Hip System

The Secur-Fit™ HA Hip System is designed with specific features to achieve immediate, initial and long-term fixation. A normalized implant geometry which enhances implant stability, bone loading, and implant to bone interlock from time of insertion, is plasma sprayed with clinically established hydroxylapatite surface treatment.

- 127° and 132° neck angle options provide proper restoration of joint kinematics and enhance head offset.
- Proximal HA surface treatment over Arc Deposit CP Ti coating.
- Distal tri-slot provides distal implant flexibility.
- Distal flutes increase rotational stability.
- Distal/proximal sizing matrix for each implant offers two distal diameters for each proximal size and two proximal sizes for each distal diameter.

http://www.osteonics.com/osteonics/hips/oshbp1.htm
Releasable 510(k) Search

Device Classification Name: PROSTHESIS, HIP, SEMI-CONSTRAINED, UNCEMENTED, METAL/POLYMER, NON-POROUS, CALICUM-PHOSPHATE

510(k) Number: K990203

Device Name: OSTEONICS PRIMARY SECUR-FIT PLUS HIP STEMS

Applicant: OSTEONICS CORP.
59 ROUTE 17
ALLENDALE, NJ 07401 1677

Contact: KATE SUTTON

Product Code: MEH

Date Received: 01/21/1999

Decision Date: 02/18/1999

Decision: SUBSTANTIALLY EQUIVALENT

Classification Advisory Committee: Orthopedic

Review Advisory Committee: Orthopedic

Statement/Summary/Purged Status: Summary only

Summary/Approval Letter Type: SUMMARY

Special

Database Updated May 10, 2000


06/07/2000
Special 510(k) - Device Modification
Summary of Safety and Effectiveness
for the
Osteonics® Primary Secur-Fit™ Plus Hip Stems

**Submission Information**

Name and Address of the Sponsor of the 510(k) Submission:
Osteonics Corporation
59 Route 17
Allendale, NJ 07401-1677

Contact Person:
Kate Sutton
Regulatory Affairs Specialist

Date of Summary Preparation:
January 18, 1999

**Device Identification**

Proprietary Name:
Osteonics® Primary Secur-Fit™™ Plus Hip Stem Series

Common Name:
Hip Prosthesis

Classification Name and Reference:
Hip Joint, Metal/Ceramic/Polymer, Semi-Constrained, Cemented or Non-Porous Uncemented Prosthesis
21 CFR §888.3353

**Predicate Device Identification**

The modified features of the Osteonics® Primary Secur-Fit™ Plus Hip Stems are substantially equivalent to features of the following Osteonics predicate device, which has been cleared for marketing via the 510(k) process:
- Osteonics® Primary Secur-Fit™™ Plus Hip Stem Series

**Device Description**

The Osteonics® Primary Secur-Fit™ Plus Hip Stems are currently marketed devices that are being modified. The modification involves the addition of two smaller sizes, 5 and 6, and elimination of
the distal tri-slot on stems with a 9mm or 10mm distal diameter. All other aspects of the Osteonics® Primary Secur-Fit™ Plus Hip Stems will remain unchanged.

**Intended Use:**

The Osteonics® Primary Secur-Fit™ Plus Hip Stems are single use components. They are intended for cementless fixation within the prepared femoral canals of patients requiring hip arthroplasty. The modified and predicate hip stems are intended to be used in conjunction with any commercially available Osteonics C-Taper femoral bearing head. For use as a total hip replacement, the modified and predicate stems may be used in conjunction with any legally marketed Osteonics acetabular component. The Osteonics® Primary Secur-Fit™ Plus Hip Stems are manufactured from titanium alloy (ASTM F-620-96). The indications for the Osteonics® Primary Secur-Fit™ Plus Hip Stems include the following:

For Use as a Bipolar Hip Replacement:
- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other Considerations:
- Pathological conditions or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty.

For Use as a Total Hip Replacement:
- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

**Performance Data:**

Mechanical testing has been performed to demonstrate the substantial equivalence of this Osteonics stem design to predicate stem designs in terms of its fatigue strength.

**Statement of Technological Comparison:**

The modification involves the addition of two smaller sizes, 5 and 6, and elimination of the distal tri-slot on stems with a 9mm or 10mm distal diameter. All other aspects of the Osteonics® Primary Secur-Fit™ Plus Hip Stems will remain unchanged.
Ms. Elizabeth A. Staub
Director, Quality Assurance
and Regulatory Affairs
Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K990203
Osteonics® Primary Secur-Fit™ Plus Hip Stem Series
Regulatory Class: II
Product Code: MEH
Dated: January 18, 1999
Received: January 21, 1999

Dear Ms. Staub:

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). This decision is based on consideration of the specific design of stem and coating composition detailed in this application. You may, therefore, market the device, subject to the general controls provisions of the Act and the following limitation:

You may not label or in any way promote these devices for "biological attachment, enhanced clinical or radiographic performance, enhanced fixation and/or long-term stable fixation." The data presented support equivalence with no additional claims over a conventional press-fit hip prosthesis (i.e., mechanical interlock, only).

Additional limitations for more specific claims of safety and effectiveness may be forthcoming. Should additional limitations be applied you will be contacted in writing to inform you of the additional labeling limitations.

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.
You may market your device under the above limitations as class II devices. These devices would be considered not substantially equivalent to a legally marketed predicate device if labeled with other intended uses and/or claims of safety or effectiveness. Any other intended uses or claims may cause the device to be classified into Class III under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing.

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 (QSR) 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. 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 immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and 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,

[Signature]

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
510(k) Number (if known): K970203

Device Name: Osteonics® Primary Secur-Fit™ Plus Hip Stems

Indications For Use:

The indications for the use of the Osteonics® Primary Secur-Fit™ Plus Hip Stems, in keeping with those of other legally marketed Osteonics femoral components, are as follows:

For Use as a Bipolar Hip Replacement:
- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other Considerations:
- Pathological conditions or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty.

For Use as a Total Hip Replacement:
- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

(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 ☐

(Optional Format 1-2-96)

(Division/Signed-Off)
Division of General Restorative Devices
510(k) Number K970203

195
INTRODUCING FROM OSTEONICS

The OMNI/FIT-™ HA
Surface Treated with Hydroxylapatite
OMNIFIT-HA™
The Right Stem with the Right Surface Treatment

The Omnifit Hip Stem Geometry . . .

- **Proximal Canal Filling Geometry** (3, 20, 21, 22, 24, 26, 27)
  This canal filling design and associated instrumentation enables exacting canal fit which minimizes stem subsidence, medial migration, and reduces peak stresses proximally.

- **Proportional Stem Design** (2, 26)
  A proportionally sized implant system provides the surgeon with the ability to fit the prosthesis to the patient and reconstruct the joint more physiologically.

- **Normalizations** (3, 12, 23, 26)
  Often referred to as intramedullary collars, normalizations are placed at 90° to the applied load. Normalizations act to convert shear to compressive stress at the bone/stem interface and help reduce medial migration and subsidence.

- **Forged Titanium Alloy**
  Provides strength and biocompatibility.

- **Ten years of Clinical Experience with this Canal Filling Geometry** (12)
  A proven implant design.

The Hydroxylapatite Surface Treatment

- **Hydroxylapatite of High Density, High Purity** (13, 15, 16, 18, 25)
  Provides proven biocompatibility and longevity. (6)

- **Calcium Phosphate Ratio close to that of bone**
  Helps minimize surface treatment resorption.

- **Fifty micron Surface Treatment Thickness** (4, 6, 14)
  Provides excellent adhesion and excellent fatigue strength.

- **Strategically Placed** (1, 8, 9)
  Located in proximal load transfer zones.

- **Extensively Evaluated** (4, 5, 6, 7, 8, 9, 17, 18, 19, 22)
  Seven years material development.
  Four years clinical experience.
Typical Radiographic Findings

Surgeon: Omar Crothers M.D.
Maine Medical Center
Portland, ME

Patient: GW
Age: 59
Weight: 225 lbs
Height: 71 inches
Diagnosis: Osteoarthritis
Stem Size: 9

Surgeon: James D'Antonio M.D.
Sewickley Valley Hospital
Sewickley, PA

Patient: LB
Age: 60
Weight: 148 lbs
Height: 70 1/2 inches
Diagnosis: Osteoarthritis
Stem Size: 11

Surgeon: William Jaffe M.D.
Hospital for Joint Diseases
Orthopaedic Institute
New York, NY

Patient: RK
Age: 30
Weight: 230 lbs
Height: 78 inches
Diagnosis: Traumatic Arthritis
Stem Size: 10

* Scores influenced by contralateral hip disease.
Findings with OMNIFIT-HA™
Two year Radiographic\textsuperscript{(10)}
Findings as determined by
a single Reviewer

Reactive Lines
0.8\% at 2 years

Calcar Atrophy
0.5\% at 2 years

Hypertrophy
3.8\% at 2 years
Function expressed as a percent of Total Population:

459 - Total No. of patients
523 - Total No. of implants
236 - Total No. of implants @ 2 years

KEY
P - Pre-op
E - Early
6 - 6 months
12 - 12 months
24 - 24 months

Pain
None/Slight

Limp
None/Mild

Support
None needed

Distance Walked
Unlimited

* The values and categories selected are as defined by the Harris Hip rating.
** Numbers are rounded to the nearest 0.10.

November 1990 Data Base
Results with Osteonics: Osmolar Components

Diagnoses

- Osteoarthritis: 62.5%
- Avascular Necrosis: 16.1%
- Rheumatoid Arthritis: 7.1%
- Revisions: 5.7%
- Other: 8.6%

Demographics

- Female to Male ratio: 1:1.18
- Average age: 51 years (range 16-81)
- Average weight: 173.2 lbs
- Bilateral patients: 64%

Harris Hip Ratings

- Pain Max Score: 44.0
- Limp Max Score: 11.0
- Support Max Score: 11.0
- Total Max Score: 100.0

- Pre-op N=523
- Early @ 6 weeks N=514
- 6 months N=500
- 12 months N=463
- 24 months N=235
References


27. Manley, M.T., Pachtman, N., Stern, L., Strain Levels in the Proximal Femur as a Function of Projected Median Stem Area, 28th Annual ORS, New Orleans LA, January 19-21, 1982 pg 250

For additional technical information see Osteonics white papers:

*Preclinical Histological Evaluation of Hydroxyapatite Implants

*Two-Year Clinical Results with Hydroxyapatite Surface Treated Femoral Components

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OMNIFIT-HA is a trademark of Osteonics Corp.

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Lit. No. LHA1

Printed in U.S.A.
<table>
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</tr>
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<tbody>
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<td>K982032</td>
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<tr>
<td>Device Name</td>
<td>OSTEONICS OMNIFIT HA HIP STEM SERIES, OSTEONICS S OSTEONICS CORP.</td>
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<tr>
<td>Applicant</td>
<td>59 ROUTE 17, ALLENDALE, NJ 07401 1677</td>
</tr>
<tr>
<td>Contact</td>
<td>KATE SUTTON</td>
</tr>
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(Database Updated May 10, 2000)
Special 510(k) - Device Modification
Summary of Safety and Effectiveness
for the
Osteonics® C-Tapered Titanium Stems

Submission Information

Name and Address of the Sponsor
of the 510(k) Submission:
Osteonics Corporation
59 Route 17
Allendale, NJ 07401-1677

Contact Person:
Kate Sutton
Regulatory Affairs Specialist

Date of Summary Preparation:
June 9, 1998

Device Identification

Proprietary Name:
Osteonics® Omnifit® HA Hip Stem Series
Osteonics® Secur-Fit™ HA Hip Stem Series
Osteonics® Primary Secur-Fit™ Plus Hip Stem Series

Common Name:
Hip Prosthesis

Classification Name and Reference:
Hip Joint, Metal/Ceramic/Polymer, Semi-Constrained, Cemented or Non-Porous
Uncemented Prosthesis
21 CFR §888.3353

Predicate Device Identification

The modified features of the Osteonics® C-Tapered Titanium Stems (Osteonics® Omnifit HA Hip Stem Series, Osteonics® Secur-Fit HA Hip Stem Series, Osteonics® Primary Secur-Fit Plus Hip Stem Series) are substantially equivalent to features of the following Osteonics predicate devices, which has been cleared for marketing via the 510(k) process:

- Osteonics® Omnifit® HA Hip Stem Series
- Osteonics® Secur-Fit™ IIA Hip Stem Series
- Osteonics® Primary Secur-Fit™ Plus Hip Stem Series
Device Description

The Osteonics® C-Tapered Titanium Stems (Osteonics® Omnifit HA Hip Stem Series, Osteonics® Secur-Fit Hip Stem Series, Osteonics® Primary Secur-Fit Plus HipStem Series) are currently marketed devices that are being modified. The modification involves shortening the trunion and reducing the diameter of the stem neck. All other aspects of the Osteonics® C-Tapered Titanium Stems will remain unchanged.

Intended Use:

The Osteonics® C-Tapered Titanium Stems are single use components. They are intended for cementless fixation within the prepared femoral canals of patients requiring hip arthroplasty. The modified hip stems are intended to be used in conjunction with any commercially available Osteonics C-Taper femoral bearing head. For use as a total hip replacement, the modified and predicate stems may be used in conjunction with any legally marketed Osteonics acetabular component. The Osteonics® C-Tapered Titanium Stems are manufactured from titanium alloy (ASTM F-620-96). The indications for the Osteonics® C-Tapered Titanium Stems include the following:

For Use as a Bipolar Hip Replacement:
- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other Considerations:
- Pathological conditions or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty.

For Use as a Total Hip Replacement:
- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

Performance Data:

Mechanical testing has been performed to demonstrate the substantial equivalence of this Osteonics stem design to predicate stem designs in terms of its fatigue strength.
Statement of Technological Comparison:

All features of the Osteonics® C-Tapered Titanium Stems (Osteonics® Omnisfit HA Hip Stem Series, Osteonics® Secur-Fit Hip Stem Series, Osteonics® Primary Secur-Fit Plus HipStem Series) will remain the same with the exception of the trunnion, which will be shortened, and the neck diameter, which will be slightly reduced.
Ms. Kate Sutton  
Regulatory Affairs Specialist  
Osteonics Corporation  
59 Route 17  
Allendale, New Jersey 07401-1677

Re: K982032  
Osteonics® C-Tapered Titanium Stems  
Regulatory Class: II  
Product Code: MEH  
Dated: June 8, 1998  
Received: June 10, 1998

Dear Ms. Sutton:

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). This decision is based on consideration of the specific design of stem and coating composition detailed in this application. You may, therefore, market the device, subject to the general controls provisions of the Act and the following limitation:

You may not label or in any way promote these devices for "biological attachment, enhanced clinical or radiographic performance, enhanced fixation and/or long-term stable fixation." The data presented support equivalence with no additional claims over a conventional press-fit hip prosthesis (i.e., mechanical interlock, only).

Additional limitations for more specific claims of safety and effectiveness may be forthcoming. Should additional limitations be applied you will be contacted in writing to inform you of the additional labeling limitations.

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.
You may market your device under the above limitations as class II devices. These devices would be considered not substantially equivalent to a legally marketed predicate device if labeled with other intended uses and/or claims of safety or effectiveness. Any other intended uses or claims may cause the device to be classified into Class III under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing.

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. 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 immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and 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,

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

Enclosure
510(k) Number (if known): K982032

Device Name: Osteonics® C-Tapered Titanium Stems

Indications For Use:

The indications for the use of the Osteonics® C-Tapered Titanium Stems, in keeping with those of other legally marketed Osteonics femoral components, are as follows:

For Use as a Bipolar Hip Replacement:
- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other Considerations:
- Pathological conditions or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty.

For Use as a Total Hip Replacement:
- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

(Please do not write below this line-continue on another page if needed)
PARTNERSHIP™ SYSTEM

Meridian™ PA Femoral Component

MERIDIAN®
PA Femoral Component

The Howmedica Partnership System unites the highest standards of science and technology to achieve a new level of surgical efficiency and clinical performance.

With the Meridian PA Femoral Component, the coating of a hip stem with hydroxyapatite has become a reality for orthopaedic surgeons who want to use a porous coated surface for biological ingrowth. Previously, HA coatings were only available on press-fit prostheses.

Howmedica Osteonics has created a technologically advanced coating that makes it possible to completely coat all areas of a porous ingrowth surface down to the metal substrate surface. The entire proximal circumferential porous surface, including the undersides of both the top and bottom layer of beads, is coated in a uniformly thin layer of precipitated hydroxyapatite, designed to be 20 microns thick so it does not block the pores for biological fixation.

The Meridian PA Femoral Component has been developed to the highest standards of the Partnership System. Now it is ready to meet the highest orthopaedic standards of quality, efficiency, and performance of all ... yours.

MERIDIAN PA:
A Proximal-Canal- Filling Straight Stem with Three-Dimensional Hydroxyapatite Coating Covering the Circumferential Porous Coating
APPLYING HIGHER STANDARDS

The Meridian PA Femoral Component incorporates many of the higher scientific and technological standards of the Partnership™ System, creating a new standard in component performance and surgical simplicity.

- V40™ Forged Femoral Head
- 3-Dimensional HA Uniform (20 micron) Coverage
- Anatomic Offset
- Circumferential Porous Coating
- GADS Forged Vitallium® Alloy
- Enhanced Canal Fit and Fill
- 18 Stem Sizes
- Polished Distal Stem
- Distal Grooves
- Gradual Taper & Rounded Distal Tip
- Distal Split
• Complete three-dimensional coverage with hydroxyapatite of porous ingrowth area.
• Thin (20 micron) uniform HA coating does not block the porosity of the ingrowth area.
• High surface area HA due to the solution deposition process.
• HA never exposed to high temperatures. Thus, no uncontrolled phase transformations (tri-calcium phosphates/calcium oxide) or partial melting of the HA and no effect on the substrate material.
• HA precipitated in a manner similar to the process of bone mineralization.
• Physiological pH (7.4) during HA precipitation.
• Anatomic offsets enhance joint stability and help restore hip biomechanics by providing the opportunity to tighten soft tissue without creating leg-length discrepancies.
• Circumferential porous coating creates a proximal seal that prevents migration of wear debris and particulate matter.
• Unique distal split and grooves are designed to improve patient comfort by reducing distal stiffness without affecting component strength. Distal stem stiffness is cited as a contributing factor in minimizing the incidence of thigh pain. 1
• Polished distal stem helps to prevent distal fixation that can interrupt and weaken proximal fixation.
• Gradual taper and rounded distal tip maintain a larger, more dispersed contact area between stem and bone than typical, blunt-tipped, rigid stems.
• Secure engagement/insertion feature simplifies component implantation. Connects the stem securely to the Command insertion/alignment instrument.
• GADS Forged Vitallium® Alloy provides the strength that makes the Meridian PA Femoral Component design and broad stem size selection possible.
  ◦ Retains fatigue strength after sintering.
  ◦ Permits extra and extra-extra small porous coated stem sizes.
• 18 Stem Sizes: 11 Proximal sizes; two distal diameters for sizes #2 through #8 for a better match of Type "A" and Type "B" canals.
• V40™ Forged Femoral Heads offer a new taper geometry for a larger range of offsets and neck lengths (-4mm to +16mm).
Circumferential View of HA Coating

Meridian ST || Meridian PA || Meridian TMZF
Definition || Reliance || Citation || Command


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succession

Secur-Fit® HA Acetabular Shell
The combination of an arc deposited CP Titanium coating with a 50-micron thick surface treatment of PureFix® HA enhances implant stability and performance.

Meridian® PA Hip System
An innovative process produces complete three-dimensional coverage of a porous ingrowth surface with precipitated hydroxyapatite.

Crossfire®
Highly crosslinked polyethylene demonstrates a 90% reduction in polyethylene wear compared to standard polyethylene.

Meridian® TMZF® Hip System
A proprietary beta titanium alloy combines the benefits of a 25% lower modulus with a 20% higher tensile strength than Ti-6Al-4V.

LEADING TO SCIENTIFIC SOLUTIONS

1-877-HOWOST 1  www.howost.com/info

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Stryker®
Howmedica
OSTEONICS

353 Veterans Boulevard
Rutherford, NJ 07070
69 Route 17 South
Allendale, NJ 07401
Releasable 510(k) Search

Device Classification Name: PROSTHESIS, HIP, SEMI-CONstrained, METAL/POLYMER, PORous UNCEMENTED
Regulation Number: 886.3358
510(k) Number: K971206
Device Name: MERIDIAN ST FEMORAL STEM AND VITALOCK SOLID BACK
Applicant: HOWMEDICA CORP.
Address: 359 VETERANS BOULEVARD
           RUTHERFORD, NJ 07070
Contact: MARGARET CROWE
Product Code: LPH
Date Received: 03/12/1997
Decision Date: 02/11/1998
Decision: SUBSTANTIALLY EQUIVALENT FOR SOME INDICATIONS
Classification Advisory Committee: Orthopedic
Review Advisory Committee: Orthopedic
Statement/Summary/Purged Status: Summary/purged 510(k)
Summary/Approval Letter: SUMMARY
Type: Traditional

CDRH Home Page  FDA Home Page  Comments  Return to Search

(Database Updated June 5, 2000)
Device: Meridian® ST Femoral Stem and Vitalock® Solid Back Shell with Peri-Apatite™ Coating

Classification Name and Reference:

Hip Joint Metal/Polymer/Metal Semi-Constrained Porous Coated Uncemented Prosthesis 21 CFR 888.3358

Proposed Regulatory Class: Class II (reclassified 1-8-93)

For information contact: Margaret F. Crowe
Manager, Regulatory Affairs
Hoechst-Roussel Inc.
359 Veterans Boulevard
Rutherford, NJ 07070
Telephone: (201) 507-7431
Fax: (201) 507-6870

The Meridian® ST Femoral Stem and Vitalock® Solid Back Shell with Peri-Apatite™ Coating are intended to be used in the primary uncemented reconstruction of the proximal femur and acetabulum damaged as a result of non-inflammatory joint disease, avascular necrosis or trauma. These devices are identical to the Meridian® ST femoral stem and Vitalock® Solid Back shell previously released under K940307, K930223, and K952397 respectively, except for the presence of a thin layer of hydroxyapatite coating applied to the porous coated surface.

The Meridian™ ST Femoral Stem and Vitalock® Solid Backed Acetabular Shell with Peri-Apatite™ Coating are equivalent to other legally marketed devices in commercial distribution. These products are listed below:

1. Meridian™ ST Femoral Stem - Hoechst-Roussel
2. Vitalock® Solid Backed Acetabular Shell - Hoechst-Roussel
3. OsteoLock™ HA Femoral Stem - Hoechst-Roussel

This equivalence is based upon similarities in intended use, material, design, and operational principles of the legally marketed devices.

Testing to characterize the Peri-Apatite™ coating was presented, along with the results of an animal study.
The APR® Hip System

For over a decade, the APR Hip System has been successfully addressing issues such as proximal fill and anatomic fit to maximize long-term stability and performance. A full range of options with three proximal body sizes for each distal diameter allow for precise patient anatomy matching.

The APR Hip System offers a complete product line to precisely match patient needs and surgeon preferences...

Non-porous
Cobalt Chromium closely matches the stiffness of cement, protecting the mantle from fatigue. The proximal cement channels aid in cement distribution compression and adhesion. Proximal and distal PMMA centralizers assure uniform cement mantle and help ensure correct positioning.

Intended only for use with bone cement.

Porous Distally Polished
Cancellous-Structured Titanium (CSTI) mimics human cancellous bone, providing a reinforced flow barrier between the proximal area and the diaphysis, which may prevent osteolytic potential AND provides for biologic fixation.

Available in Standard and Large Bodies

Porous Distally Textured
Grit-blasted surface technology provides a stable fixation of the stem.

The collared stem loads the calcar to resist subsidence. The collarless stem suits the needs of surgeons who believe the stem should find its natural place.

Available in Standard, Large and Oversized Bodies

Porous HA Distally Textured
Sulzer Orthopedics is the first company to offer Hydroxyapatite (HA) coating over CSTI. HA porous surfaces encourage effective filling of the proximal femur, avoiding further degeneration.

Available in Standard, Large and Oversized Bodies
Nonporous Fully Textured
With the same geometry as the porous option but without the porous coating, the fully textured stem offers a lower-cost press-fit option to cementing.

Available in Large and Oversized Bodies

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Releasable 510(k) Search

Device Classification Name: PROSTHESIS, HIP, SEMI-CONSTRAINED, METAL/POLYMER, POROUS UNCEMENTED
Regulation Number: 888.3358
510(k) Number: K973124
Device Name: APR POROUS HA HIP SYSTEM
Applicant: SULZER ORTHOPEDICS, INC.
Address: 9900 SPECTRUM DR.
City: AUSTIN, TX 78717
Lori K Holder
Contact: LPH
Date Received: 08/20/1997
Decision Date: 11/03/1997
Decision: SUBSTANTIALLY EQUIVALENT FOR SOME INDICATIONS
Classification Advisory Committee: Orthopedic
Review Advisory Committee: Orthopedic
Statement/Summary/Purged Status: Summary only
Summary/Approval Letter: SUMMARY
Type: Traditional

(Database Updated May 10, 2000)
Lori Kleinschrodt Holder, RAC
Regulatory Affairs Specialist
Sulzer Orthopedics Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K973124
APR Porous HA Hip Stem
Regulatory Class: II
Product Codes: LPH and MEH
Dated: August 19, 1997
Received: August 20, 1997

Dear Ms. Holder:

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). This decision is based on consideration of the specific design of stem and coating composition detailed in this application. You may, therefore, market the device, subject to the general controls provisions of the Act and the following limitation:

You may not label or in any way promote these devices for enhanced clinical or radiographic performance, enhanced biological fixation and/or long-term stable fixation. The data presented support equivalence with no additional claims over a conventional porous-coated uncemented hip prosthesis (i.e., biological fixation, only).

Additional limitations for more specific claims of safety and effectiveness may be forthcoming. Should additional limitations be applied you will be contacted in writing to inform you of the additional labeling limitations.

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.
You may market your device under the above limitations as class II devices. These devices would be considered not substantially equivalent to a legally marketed predicate device if labeled with other intended uses and/or claims of safety or effectiveness. Any other intended uses or claims may cause the device to be classified into Class III under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing.

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 requirements, 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. 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 immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and 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,

[Signature]

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
510(k) Number (if known): k973124

Device Name: APR Porous HA System

Indications For Use:

1. Patient conditions of non-inflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis and inflammatory joint disease (IID), e.g., rheumatoid arthritis.

2. Those patients with failed previous surgery where pain, deformity, or dysfunction persists.

3. Revision of previously failed arthroplasty.

The APR Porous HA System is intended only for use without bone cement.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use

Division Sign-Off
Division of General Restorative Devices
510(k) Number k973124

(Optional Format 1-2-96)

228
In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a 510(k) Summary for the APR Porous HA Hip Stem.

Submitter:  Sulzer Orthopedics, Inc.
            9900 Spectrum Drive
            Austin, Texas 78717
            (512) 432-9900

Date:  August 19, 1997

Contact Person:  Jacquelyn Hughes
                Manager, Regulatory Affairs

Classification Name:  Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis, 21 CFR 888.3358.

Common/Usual Name:  Biologically fixed total hip prosthesis, semi-constrained

Trade/Proprietary Name:  APR Porous HA Hip Stem

PRODUCT DESCRIPTION

The APR Porous HA femoral stem is anatomically designed with right and left components. These stems are available in three proximal body styles to optimize fit of the hip stem in the femoral canal: a standard body, a large body in which the proximal anterior dimension has been widened slightly to maximize filling of the proximal femur, and an oversized for the patient exhibiting the endosteal canal shape (sometimes referred to as Type A) in which the diaphysis is disproportionately smaller than the metaphysis. The larger sizes of the stems are stems feature distal hollowing for increased stem flexibility.

The stems are manufactured from wrought Ti-6Al-4V (ASTM F-136). The stems are fabricated with a neck and stem designed to match the natural shape and curve of the femur. Ceramic hydroxylapatite (HA) coated Cancellous-Structured Titanium (CSTi) is located on the inferior side of the collar as well as the proximal femoral body. A morse-type taper on the proximal aspect of the stem permits attachment of one of a variety of femoral heads.

This device is intended for use with the following previously cleared devices:

- IOI metallic femoral bearing heads
- IOI Biolox Bearing Heads
- Zirconia Bearing Heads
- IOI acetabular components
SPECIFIC DIAGNOSTIC INDICATIONS

The APR Porous HA Hip Stem is intended to replace the anatomy of the femur in cases of total hip or hemi-hip replacement. The general indications associated with the use of the APR Porous HA Hip Stem in total hip arthroplasty include:

1. Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
2. Those patients with failed previous surgery where pain, deformity, or dysfunction persists.
3. Revision of previously failed hip arthroplasty

Total hip replacements may be considered for younger patients if any unequivocal indication outweighs the risks associated with the age of the patient, and modified demands regarding activity and hip joint loading are assured. This includes severely crippled patients with multiple joint involvement, for whom an immediate need of hip mobility leads to an expectation of significant improvement in the quality of their lives.

The APR Porous HA Hip Stem is intended only for use without bone cement in the United States. This device is intended for single use only.

SUBSTANTIAL EQUIVALENCE

The APR Porous HA Hip Stem is substantially equivalent to the Natural-Hip HA Stem (Sulzer Orthopedics Inc.) and the APR Universal Hip Stem with Calcitite®-Coated CSTI (Sulzer Orthopedics Inc.).