

K072531

510(k) Summary  
Smith & Nephew

DEC 06 2007

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| Submitter's Name:                 | Smith & Nephew, Inc., Orthopaedic Division  |
| Submitter's Address:              | 1450 Brooks Road, Memphis, TN 38116   |
| Submitter's Telephone Number:     | 901-399-5340  |
| Contact Person:                   | Megan Bevill  |
| Date Summary Prepared:            | September 6, 2007   |
| Trade or Proprietary Device Name: | Legion Stems with Holes   |
| Common or Usual Name:             | Knee Prosthesis   |
| Classification Name:              | 21 CFR 888.3560 Knee joint patellofemorotibial<br>polymer/metal/polymer semi-constrained cemented<br>prosthesis |
| Device Class:                     | Class II  |
| Panel Code:                       | Orthopaedics/87/JWH   |

**Device Description**

The subject stems are revision stems manufactured from titanium alloy which feature distal fixation holes. The stems will be available in a variety of lengths and diameters, and they will be used in conjunction with currently marketed femoral and tibial components of the Legion Revision Knee System.

**Intended Use and Indications**

Intended Use:

The subject Legion Stems with Holes are intended to be used with femoral and tibial components of the Legion Revision Knee System.

Indications:

The Revision Knee System Components are indicated for:

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity levels are compatible with an adequate long-term result.
3. Failed osteotomies, unicompartamental replacement, or total knee replacement.
4. The constrained knee systems are designed for use in patients in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligament) are absent or incompetent.

**Substantial Equivalence**

Predicate stems:

Smith & Nephew Legion Press-Fit Stem  
Smith & Nephew TriGen Knee Nail

The subject stems are substantially equivalent to the above named stems in indications for use, material, method of manufacture, and basic design principles. The distal fixation mechanism is substantially equivalent to the TriGen Knee Nail listed above.



DEC 06 2007

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Smith & Nephew, Inc.  
Orthopaedic Division  
% Megan Bevill  
Regulatory Affairs Specialist  
1450 Brooks Road  
Memphis, Tennessee 38116

Re: K072531

Trade/Device Name: Legion Stem with Holes  
Regulation Number: 21 CFR 888.3560  
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained  
cemented prosthesis  
Regulatory Class: Class II  
Product Code: JWH  
Dated: September 6 2007  
Received: September 7, 2007

Dear Ms. Bevill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure

# Indications for Use

510(k) Number (if known): K072531

Device Name: Legion Stems with Holes

The Revision Knee System Components are indicated for:

1. Rheumatoid arthritis.
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3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
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Prescription Use   
(Part 21 CFR 801 Subpart D)

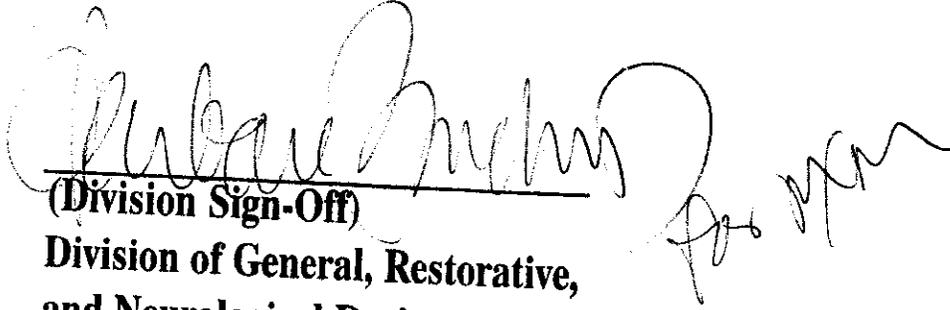
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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