Dear Ana Roca:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);
and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

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

Enclosure
Indications for Use

510(k) Number (if known)
K172872

Device Name
DePuy Synthes Femoral Neck System

Indications for Use (Describe)

The Femoral Neck System (FNS) is indicated for basilar femoral neck fractures in adults and adolescents (12-21) in which the growth plates have fused or will not be crossed.

Type of Use (Select one or both, as applicable)

☑ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASTaff@fda.hhs.gov

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.*
| **Sponsor** | DePuy Synthes  
Ana Sala Roca  
Luzernstrasse 21  
4528 Zuchwil, Switzerland  
Phone: +41 32 720 45 73  
Fax: +41 32 720 71 73 |
<table>
<thead>
<tr>
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<tbody>
<tr>
<td><strong>Date Prepared</strong></td>
<td>March 01, 2018</td>
</tr>
<tr>
<td><strong>Proprietary Name</strong></td>
<td>DePuy Synthes Femoral Neck System</td>
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<tr>
<td><strong>Classification Name</strong></td>
<td>Single/multiple component metallic bone fixation appliances and accessories</td>
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</table>
| **Classification** | Class II  
Regulation Number: 21 CFR 888.3030  
Product Code: KTT |
| **Predicate device** | **Predicate device:**  
Synthes Dynamic Hip Screw System (K791619)  
**Predicate device:**  
Omega 3 System (K062066) |
| **Reference Device** | **Reference Device:**  
Synthes Titanium Limited Contact Dynamic Hip Screw (Ti.LC-DHS) Implant System (K953607)  
**Reference Device:**  
DePuy Synthes 4.0 mm and 4.5 mm Cortex Screws,  
DePuy Synthes 2.4 mm Cannulated Screws,  
DePuy Synthes 3.5 mm and 4.0 mm Cannulated Screws,  
DePuy Synthes 4.5 mm Cannulated Screws,  
**DePuy Synthes 6.5 mm Cannulated Screws,**  
DePuy Synthes 7.0 mm and 7.3 mm Cannulated Screws,  
DePuy Synthes 1.5 mm Headless Compression Screws,  
DePuy Synthes 2.4 mm Headless Compression Screws,  
DePuy Synthes 3.0 mm Headless Compression Screws,  
DePuy Synthes 4.5 mm and 6.5 mm Headless Compression Screw (K161616) |
| **Device Description** | The subject Femoral Neck System is comprised of implants designed to treat basilar femoral neck fractures as well as system-specific insertion instruments. The Femoral Neck System is a modular system consisting of four connected implant components forming a fixed-angle gliding fixation device which allows for controlled collapse of the femoral head. |
The implants are manufactured from Titanium Alloy and are provided in a range of dimensions. The same construct can be used for the left and right femur.

### Indications for Use

The Femoral Neck System (FNS) is indicated for basilar femoral neck fractures in adults and adolescents (12-21) in which the growth plates have fused or will not be crossed.

### Non-clinical Performance Data

Static bending, cyclic fatigue and rotational resistance testing of constructs has been performed to compare the subject DePuy Synthes Femoral Neck System to the Predicate device Dynamic Hip Screw System. This information supports that the mechanical performance of the subject system is at least equivalent to that of the Predicate device.

Magnetic Resonance compatibility testing has been performed to establish MR Conditional parameters for the subject DePuy Synthes Femoral Neck System.

The devices also meet the specified endotoxin requirement of 20EU/device using the LAL test method.

### Clinical Performance Data

Clinical testing was not necessary for the determination of substantial equivalence.

### Comparison to Predicate

The subject system has similar intended use as the Predicate devices. The indications of the subject system are a subset of the indications of the Predicate devices.

The subject system, like the Predicate devices, is a fixed-angle fixation device that allows for controlled collapse of the femoral head. These systems are modular systems applied through a standard lateral approach and fixed on the lateral cortex of the femur. Systems are available sterile.

The subject system presents several technological characteristics that are not found in the Predicate devices:

- In contrast to the Predicate devices, the plates of the subject system are available with a one hole design.

- When compared to the Predicate devices, the subject system features an additional fixation point in the femoral head by design. In addition, the sliding component of the subject system comprises two interlocked parts instead of one.

- While the Subject device is made from Titanium Alloy (TiAl6Nb7), the Predicate devices are made from Stainless Steel (316L).

Mechanical testing demonstrates substantial equivalence of the Subject device to the Predicate DHS device in regards to mechanical strength. Furthermore, the subject system and the reference device (K953607), both used in the same anatomical location and with a similar intended use, are made from Titanium Alloy (TiAl6Nb7).
Both Predicate devices provide the surgeon with an option for a second point of fixation in the femoral head and result in a construct configuration that occupies a similar volume and position in the femoral neck and head.

It can be concluded that features of the Subject device are substantially equivalent to the Predicate devices based on the similarities in intended use and design.

<table>
<thead>
<tr>
<th>Substantial Equivalence</th>
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<tbody>
<tr>
<td>The subject system has similar intended use as the predicate and reference devices. The subject system has similar indications for use and it is similar in design and fundamental technology as compared to the Predicate devices. The raw material type of the subject system and reference device is the same.</td>
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<tr>
<td>The mechanical testing included in this submission supports that:</td>
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<tr>
<td>• Any differences in technological characteristics from the Predicate devices do not raise any new questions of safety and effectiveness.</td>
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<tr>
<td>• The Subject devices are at least as safe and effective as the Predicate devices.</td>
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<tr>
<td>It is concluded that the information provided in this submission supports substantial equivalence.</td>
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