DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 16, 2017

Synthes USA Products, LLC
Nina Rudolph
Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K161616
Trade/Device Name: 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
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: January 25, 2017
Received: January 27, 2017

Dear Ms. Rudolph:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161616

Device Name
DePuy Synthes 2.4 mm Cannulated Screws

Indications for Use *(Describe)*
The DePuy Synthes 2.4 mm Cannulated Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of small bones in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161616

Device Name
DePuy Synthes 4.0 mm and 4.5 mm Cortex Screws

Indications for Use *(Describe)*
The DePuy Synthes 4.0 mm Cortex Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, tibia, calcaneus, femur, fibula, and the bones of the foot and hand in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The DePuy Synthes 4.5 mm Cortex Screws are intended for fixation of fractures, fusion, osteotomies, non-unions, and malunions of various long bones, such as the humerus, femur and tibia; the pelvis, and the bones of the foot and hand in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

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

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510(k) Number *(if known)*

K161616

Device Name
DePuy Synthes 3.5 mm and 4.0 mm Cannulated Screws

Indications for Use *(Describe)*
The DePuy Synthes 3.5 mm and 4.0 mm Cannulated Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of small bones and small bone fragments in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

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

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510(k) Number *(if known)*

K161616

Device Name
DePuy Synthes 4.5 mm Cannulated Screws

Indications for Use *(Describe)*
The DePuy Synthes 4.5 mm Cannulated Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of long bones and long bone fragments; and the bones of the hand and foot, in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

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

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See PRA Statement below.

510(k) Number *(if known)*

K161616

Device Name
DePuy Synthes 6.5 mm Cannulated Screws

Indications for Use *(Describe)*

The DePuy Synthes 6.5 mm Cannulated Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of long bones and long bone fragments, pelvis, sacrum, and the bones of the foot in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation. These screws are also indicated for femoral neck fractures; slipped capital femoral epiphysis; an adjunct to DHS in basilar neck fractures; tibial plateau fractures; ankle arthrodesis; pediatric femoral neck fractures; intercondylar femur fractures; SI joint disruptions; and subtalar arthrodesis.

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

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See PRA Statement below.

510(k) Number *(if known)*

K161616

Device Name
DePuy Synthes 7.0 mm and 7.3 mm Cannulated Screws

Indications for Use *(Describe)*

The DePuy Synthes 7.0 mm and 7.3 mm Cannulated Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of long bones and long bone fragments, pelvis, sacrum, and the bones of the foot in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation. These screws are also indicated for slipped capital femoral epiphysis; ankle arthrodesis; and subtalar arthrodesis.

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)

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See PRA Statement below.

510(k) Number *(if known)*

K161616

Device Name

DePuy Synthes 1.5 mm Headless Compression Screws

Indications for Use *(Describe)*

The DePuy Synthes 1.5 mm Headless Compression Screws are intended for fixation of intra-articular and extra-articular fractures, avulsions, non-unions, malunions, and osteotomies of small bones and small bone fragments, as well as arthrodesis of small joints in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

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

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See PRA Statement below.

510(k) Number *(if known)*

K161616

Device Name
DePuy Synthes 2.4 mm Headless Compression Screws

Indications for Use *(Describe)*
The DePuy Synthes 2.4 mm Headless Compression Screws are intended for fixation of fractures, osteotomies, non-unions, and malunions of small bones and small bone arthrodesis in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

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)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K161616

Device Name
DePuy Synthes 3.0 mm Headless Compression Screws

Indications for Use *(Describe)*

The DePuy Synthes 3.0 mm Headless Compression Screws are intended for fixation of intra-articular and extra-articular fractures, non-unions, malunions, and osteotomies of small bones and small bone fragments, as well as arthrodesis of small joints in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

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)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K161616

Device Name
DePuy Synthes 4.5 mm and 6.5 mm Headless Compression Screws

Indications for Use *(Describe)*
The DePuy Synthes 4.5 mm and 6.5 mm Headless Compression Screws are indicated for fixation of fractures, fusions, osteotomies, non-unions, and malunions of various bones and bone fragments including bones of the foot, humerus, femur and tibia in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

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)

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5. 510(k) Summary

Date Prepared: February 14, 2017

Submitter:
Synthes USA Products, LLC
1301 Goshen Parkway
West Chester, PA 19380
United States of America

Contact:
Nina Rudolph
Regulatory Affairs Specialist
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-6935
Nrudolph@its.jnj.com

Device Name:
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, and
DePuy Synthes 4.5 mm and 6.5 mm Headless Compression Screws.

Classification Name: Smooth or threaded metallic bone fixation fastener

Regulatory Class: II

Product Code: HWC (Screw, Fixation, Bone)
21 CFR §888.3040

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5.1. Predicate Devices

Primary Predicate Devices:

Table 2 details the subject devices and the associated primary predicate.

Table 1: Primary Predicate Device Table

Subject Device	Primary Predicate
DePuy Synthes 4.0 mm and 4.5 mm Cortex Screws	**K112583** – Synthes Cortex Screws 4.0 mm and 4.5 mm Cortex Screws
DePuy Synthes 2.4 mm Cannulated Screws	**K012945** – Synthes 2.4 mm Cannulated Screw
DePuy Synthes 3.5 mm and 4.0 mm Cannulated Screws	**K963192** – Synthes Sterile 3.5 mm and 4.0 mm Cannulated Screws
DePuy Synthes 4.5 mm Cannulated Screw	**K963172** – Synthes Sterile 4.5 mm Cannulated Screw
DePuy Synthes 6.5 mm Cannulated Screw	**K021932** – Synthes 6.5 mm Cannulated Screw
DePuy Synthes 7.0 mm and 7.3 mm Cannulated Screws	**K962011** – Synthes 7.0 mm and 7.3 mm Cannulated Screws
DePuy Synthes 1.5 mm Headless Compression Screws	**K090949** – Synthes 1.5 mm Headless Compression Screws
DePuy Synthes 2.4 mm Headless Compression Screws	**K012945** – Synthes 2.4 mm Cannulated Screw
DePuy Synthes 3.0 mm Headless Compression Screws	**K050636** – Synthes 3.0 mm Headless Compression Screws
DePuy Synthes 4.5 mm and 6.5 mm Headless Compression Screws	**K080943** – Synthes 4.5 mm and 6.5 mm Headless Compression Screws

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Additional Predicate Device:

Comparison to an additional predicate, Synthes 2.4 mm Cannulated Compression Screw (K021556), is used in support of the design changes disclosed in this submission to Synthes 2.4 mm Cannulated Screw (K012945). The design changes resulted in new part numbers referred to as the DePuy Synthes 2.4 mm Headless Compression Screws.

Table 2: Additional Predicate Device Table

Subject Device	Additional Predicate
DePuy Synthes 2.4 mm Headless Compression Screws	**K021556** – Synthes 2.4 mm Cannulated Compression Screw

5.2. Device Description

The DePuy Synthes Cortex, Cannulated, and Headless Compression Screws are metallic bone screws manufactured from Stainless Steel (ASTM F138), Commercially Pure Titanium (ASTM F67), and/or Titanium Alloy (ASTM F1295). The screws are available in multiple lengths and diameters, and are intended to be used as stand-alone bone screws for internal bone fixation of fractures, fusions, osteotomies, non-unions, and malunions in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by the screw fixation.

The DePuy Synthes Cannulated and Headless Compression screws are cannulated for use with guidewires for precise placement in bone with the exception of the 1.5 mm Headless Compression Screw, which is a solid screw and therefore does not allow for instrumentation with a guide wire. The Headless Compression Screws feature threaded heads that allow for purchase in the near cortex of bone during and after implantation, potentially reducing complications associated with countersinking of traditional cortex or cannulated screws.

5.3. Indications for Use

The DePuy Synthes 4.0 mm Cortex Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, tibia, calcaneus, femur, fibula, and the bones of the foot and hand in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The DePuy Synthes 4.5 mm Cortex Screws are intended for fixation of fractures, fusion, osteotomies, non-unions, and malunions of various long bones, such as the humerus, femur and tibia; the pelvis, and the bones of the foot and hand in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

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The DePuy Synthes 2.4 mm Cannulated Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of small bones in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The DePuy Synthes 3.5 mm and 4.0 mm Cannulated Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of small bones and small bone fragments in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The DePuy Synthes 4.5 mm Cannulated Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of long bones and long bone fragments; and the bones of the hand and foot, in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The DePuy Synthes 6.5 mm Cannulated Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of long bones and long bone fragments, pelvis, sacrum, and the bones of the foot in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation. These screws are also indicated for femoral neck fractures; slipped capital femoral epiphysis; an adjunct to DHS in basilar neck fractures; tibial plateau fractures; ankle arthrodesis; pediatric femoral neck fractures; intercondylar femur fractures; SI joint disruptions; and subtalar arthrodesis.

The DePuy Synthes 7.0 mm and 7.3 mm Cannulated Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of long bones and long bone fragments, pelvis, sacrum, and the bones of the foot in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation. These screws are also indicated for slipped capital femoral epiphysis; ankle arthrodesis; and subtalar arthrodesis.

The DePuy Synthes 1.5 mm Headless Compression Screws are intended for fixation of intra-articular and extra-articular fractures, avulsions, non-unions, malunions, and osteotomies of small bones and small bone fragments, as well as arthrodesis of small joints in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The DePuy Synthes 2.4 mm Headless Compression Screws are intended for fixation of fractures, osteotomies, non-unions, and malunions of small bones and small bone arthrodesis in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The DePuy Synthes 3.0 mm Headless Compression Screws are intended for fixation of intra-articular and extra-articular fractures, non-unions, malunions, and osteotomies of small bones and small bone fragments, as well as arthrodesis of small joints in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The DePuy Synthes 4.5 mm and 6.5 mm Headless Compression Screws are indicated for fixation of fractures, fusions, osteotomies, non-unions, and malunions of various bones and bone fragments including bones of the foot, humerus, femur and tibia in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

Discussion:

Both the subject devices and the primary predicate devices share the same intended use; comparison of the indications of the subject and predicate device in addition to positive results from the provided clinical literature demonstrate that the proposed changes to the Indications for Use of the subject devices supports substantial equivalence.

5.4. Comparison of Technological Characteristics with the Predicate Device

Cortex Screws:

Technological characteristics of the cortex screws include features such as thread form, tip design, and recess type, dimensions such as length and diameter, material of construction, and sterility. A comparison table of the subject devices and the predicate devices technological characteristics are provided within the submission.

There have been no design changes to the DePuy Synthes Cortex Screws 4.0 mm and 4.5 mm Cortex Screws since the previous clearance (K112583). Therefore, there are no differences in technological characteristics in comparison to the predicate device (K112583) that raise new questions of safety and efficacy.

Cannulated Screws:

Technological characteristics of the cannulated screws include features such as thread form, tip design, and recess type, dimensions such as length and diameter, material of construction, and sterility. A comparison table of the subject devices and the predicate devices technological characteristics are provided within the submission.

Design changes resulting in additional part numbers to Synthes 2.4 mm Cannulated Screw (K012945), Synthes Sterile 3.5 mm and 4.0 mm Cannulated Screws (K963192), Synthes Sterile 4.5 mm Cannulated Screw (K963172), and Synthes 7.0 mm and 7.3 mm Cannulated Screws

(K962011) were assessed per FDA's Guidance Document entitled "*Deciding When to Submit a 510(k) for a Change to an Existing Device"* issued January 10, 1997 and resulted in internal documentation. DePuy Synthes also offers Synthes 3.5 mm and 4.0 mm Cannulated Screws (K963192), Synthes 4.5 mm Cannulated Screw (K963172), and Synthes 7.0 mm and 7.3 mm Cannulated Screws (K962011) non-sterile, whereas the previous submission of these devices was for sterile devices only. Per FDA's Guidance Document entitled "*Deciding When to Submit a 510(k) for a Change to an Existing Device"* issued January 10, 1997 there is no change in the SAL of the devices since their previous clearance, and therefore, there are no new issues of safety and efficacy. There have been no design changes to the Synthes 6.5 mm Cannulated Screws previously cleared in K021932. Therefore, there are no differences in technological characteristics of the subject devices in comparison to the predicate devices that raise new questions of safety and efficacy.

Headless Compression Screws:

Technological characteristics of the Headless Compression Screws include features such as thread form, tip design, and recess type, dimensions such as length and diameter, material of construction, and sterility. A comparison table of the subject devices and the predicate devices technological characteristics are provided within the submission.

Design changes and additional part numbers to Synthes 2.4 mm Cannulated Screw (K012945) include 2.4 mm Headless Compression Screws. The changes were assessed per FDA's Guidance Document entitled "*Deciding When to Submit a 510(k) for a Change to an Existing Device"* issued January 10, 1997 and resulted in documentation. Additionally, there have been no design changes to the Headless Compression Screws previously cleared in K090949, K050636, and K080943. Therefore, there are no differences in technological characteristics of the subject devices in comparison to the predicate devices that raise new questions of safety and efficacy.

5.5. Performance Data

Bench:

There is no bench testing included in this submission.

Animal:

There is no animal data included in this submission.

Clinical:

This submission contains published clinical literature to support the safety and efficacy of the modifications to the Indications for Use of the DePuy Synthes Cortex, Cannulated, and Headless Compression Screws. The positive clinical outcomes from the clinical literature and comparison

to predicate devices provided in the submission demonstrate that the modifications to the Indications for Use supports substantial equivalence.

Non-Clinical:

Bacterial Endotoxin Testing was conducted and met the specified endotoxin limits.

Conclusions

The intent of this submission is to modify the indications for use for the DePuy Synthes Cortex, Cannulated, and Headless Compression Screws and to disclose design changes and additional part numbers to the subject devices since their previous clearance.

- Published clinical literature supports that the modifications to the Indications for Use for the subject devices.
- Design changes were assessed per FDA's Guidance Document entitled "*Deciding When to Submit a 510(k) for a Change to an Existing Device"* issued January 10, 1997 and resulted in internal documentation.
- There have been no design changes to any of the other subject devices since their previous clearance, and as a result, there are no differences in technological characteristics in comparison to the predicate devices for those devices that raise *different* questions of safety and efficacy.

The proposed Cortex, Cannulated, and Headless Compression Screws have similar Indications for Use, share the same design characteristics, incorporate the same fundamental product technology, and are composed of the same materials when compared to the previous clearance of the devices which serve as the predicate devices. It is concluded that the information included in this submission supports substantial equivalence.