June 29, 2021

Smith & Nephew, Inc.
Thomas Fearnley
Senior Regulatory Affairs Specialist
1450 E Brooks Rd
Memphis, Tennessee 38116

Re: K210837
Trade/Device Name: Smith & Nephew Plates and Screws
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: JDO, KTT, HRS, HWC, HTN, NDG, HTY
Dated: May 28, 2021
Received: June 1, 2021

Dear Thomas Fearnley:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210837

Device Name
Compression Hip Screw (CHS)

Indications for Use *(Describe)*

Adult Indications

1. Intracapsular fractures of the femoral neck. (For high subcapsular fractures it may be more prudent to select a prosthesis in lieu of internal fixation to reduce the risk of a nonunion or avascular necrosis of the femoral head.)
2. Trochanteric or subtrochanteric fractures with appropriate additional postoperative precautions about weight bearing and more than sedentary activity.
3. Osteotomies for patients with diseases or deformities of the hip.
4. Hip arthrodesis.
5. Supracondylar fractures and distal femoral fractures using a supracondylar plate.
6. Ipsilateral femoral shaft/neck fractures.□

Pediatric Indications

1. Congenital coxa vara.
2. Congenital dislocation of the hip.
3. Subluxation or dislocation secondary to neurologic disorders such as cerebral palsy, myelomenigocele, poliomyelitis, etc. Usually valgus-anteversion deformities.
4. Coxa plana (Legg-Calve-Perthes disease) for containment of the head completely within the acetabulum.

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.

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210837

Device Name
CONQUEST FN

Indications for Use *(Describe)*
CONQUEST FN is indicated for displaced and undisplaced intracapsular femoral neck fractures.

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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510(k) Number *(if known)*
K210837

Device Name
D-Rad

Indications for Use *(Describe)*
The D-RAD SMART PACK System is intended for the fixation of fractures involving the distal radius.

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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510(k) Number *(if known)*
K210837

Device Name
EVOS

Indications for Use *(Describe)*
The EVOS MINI Plating System is indicated for adolescent (12–18 years) and transitional adolescent (18–21 years) subpopulations and adults, as well as patients with osteopenic bone.

The EVOS MINI Plating System is indicated for fracture fixation, arthrodesis, reconstruction, replantation or reduction of small bones and small bone fragments. This system is also indicated for non-load bearing stabilization and reduction of bone fragments in long bones.

The EVOS Small Fragment Plating System is indicated for adult and adolescent (greater than 12-21 years of age) patients, as well as patients with osteopenic bone. It is indicated for fixation of small and long bone fractures, including, but not limited to, those of the tibia, fibula, femur, humerus, ulna, radius, pelvis, acetabulum, metacarpals, metatarsals, and clavicle.

The EVOS Partial Articular and Anti-Glide Plates are indicated for the treatment of partial articular fractures of the distal and proximal tibia (AO/OTA Fracture Classifications Type B), and for fracture fixation of the fibula.

The EVOS Wrist Fracture Plating System is indicated for adult and pediatric patients, as well as patients with osteopenic bone. It is indicated for fixation of fractures, malunions, and osteotomies involving the radius and ulna.

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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510(k) Number *(if known)*

Device Name
PERI-LOC

Indications for Use *(Describe)*

The PERI-LOC Plate and Screw System can be used for adult and pediatric patients, as well as patients with osteopenic bone. PERI-LOC bone plates and bone screws are indicated for fixation of pelvic, small and long bone fractures, including those of the tibia, fibula, femur, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, radius, calcaneus, and clavicle.

PERI-LOC Periarticular Locked Plating System VLP Plates and Screws can be used for adult and pediatric patients, as well as patients with osteopenic bone. PERI-LOC contoured VLP Plates and Screws are indicated for partial articular fractures (AO/OTA Fracture Classification Type B) of the distal and proximal tibia, and for fracture fixation of the fibula. PERI-LOC VLP One-Third Tubular Locking Plates are indicated for, but not limited to, fixation of fractures, non-unions and osteotomies of the medial malleolus, fibula, distal ulna, olecranon, calcaneus and metatarsals.

PERI-LOC Periarticular Locked Plating System Proximal Femur Bone Plates, Bone Screws and Cable Accessories can be used for adult patients as well as patients with osteopenic bone. PERI-LOC Proximal Femur Bone Plates, Bone Screws and Cable Accessories are indicated for fractures of the trochanteric region including simple intertrochanteric, reverse oblique trochanteric, transverse trochanteric, complex multi-fragmentary, and fractures with medial cortex instability; proximal femur fractures combined with ipsilateral shaft fractures; pathological fractures of the proximal femur including metastatic fractures; proximal femur osteotomies; fixation of fractures in osteopenic bone; fixation of nonunions and malunions; basi/transcervical femoral neck fractures; subcapital femoral neck fractures; and subtrochanteric femur fractures.

The Smith & Nephew VLP FOOT Plating System can be used in adolescent (12-18 years) and transitional adolescent (18-21 years) subpopulations and adults, as well as patients with osteopenic bone. The VLP FOOT Plating System is indicated for fracture fixation, reconstruction or arthrodeses of small bones, including those in the forefoot, midfoot and hindfoot.

The Smith & Nephew PERI-LOC Ankle Fusion Plating System can be used in adolescent (12-18 years) and transitional adolescent (18-21 years) subpopulations and adults, as well as patients with osteopenic bone. The PERI-LOC Ankle Fusion Plating System is indicated for ankle arthrodesis and fractures, including the distal tibia, talus and calcaneus.

The VLP MINI-MOD Small Bone Plating System and VLP MINI-MOD Talus Plates are indicated for adolescent (12–18 years) and transitional adolescent (18–21 years) subpopulations and adults, as well as patients with osteopenic bone.

The VLP MINI-MOD Small Bone Plating System is indicated for fracture fixation, arthrodesis, reconstruction, replantation or reduction of small bones and small bone fragments. This system is also indicated for non-load bearing stabilization and reduction of bone fragments in long bones.

The VLP MINI-MOD Talus Plates are indicated for fracture fixation, reconstruction or arthrodesis of small bones, including those in the forefoot, midfoot and hindfoot.

The VLP Wrist Fracture System Radial Plates are indicated for fixation of fractures, malunions, and osteotomies involving the radius.

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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510(k) Number *(if known)*
K210837

Device Name
TC-100

Indications for Use *(Describe)*

Bone plates and screws from the Smith & Nephew Bone Plate System are used for adult and pediatric patients as indicated for pelvic, small, and long bone fracture fixation. Indications for use include fractures of the tibia, fibula, femoral condyle, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, middle hand and middle foot bones; treatment of the calcaneus; hip arthrodesis, and provisional hole 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210837

Device Name
Cannulated Screws

Indications for Use *(Describe)*
Bone plates and screws from the Smith & Nephew Bone Plate System are used for adult and pediatric patients as indicated for pelvic, small, and long bone fracture fixation. Indications for use include fractures of the tibia, fibula, femoral condyle, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, middle hand and middle foot bones; treatment of the calcaneus; hip arthrodesis, and provisional hole fixation.

The 4.0mm Cannulated Screws and associated washers are additionally intended for arthrodesis and osteotomies of small bones and small joints, including scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, patella, ulnar styloid, capitellum, radial head and radial styloid.

The 5.5mm, 6.5mm, 7.0mm, and 8.0mm Cannulated Screws and associated washers are additionally intended for reconstruction, osteotomy, and arthrodesis of various bones and bone fragments appropriate for the size of the device including joint fusions (arthrodesis) in the foot and ankle.

The Smith & Nephew 2.5mm, 3.0mm Cannulated and 3.0mm Headless Compression Screws are intended for fixation of intraarticular and extra-articular fractures and non-unions of small bones and small bone fragments; arthrodeses of small joints; bunionectomies and osteotomies; scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, patella, ulnar styloid, capitellum, radial head and radial styloid.

The Smith & Nephew 2.0mm QFX Screw is indicated for osteotomies of the lesser metatarsals, such as Weil osteotomies. Osteotomies, fusions and fractures of the phalanges, metacarpals and carpals of the hand.

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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Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	May 28, 2021
Contact Person and Address:	Thomas Fearnley Senior Regulatory Affairs Specialist T 901-399-1224
Name of Device:	Smith & Nephew, Inc. Plates and Screws Systems: EVOS, Peri-Loc, D-Rad, TC-100, VLP Mini-Mod, Compression Hip Screw (CHS), CONQUEST FN, and cannulated screws
Common Name:	Bone Plates and Screws
Device Classification Name and Reference:	21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories. 21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	JDO, KTT, HRS, HWC, HTN, NDG, HTY
Predicate Device:	Smith & Nephew Plates and Screws Systems: EVOS (K201527), Peri-Loc (K120667), D-Rad (K161665), TC-100 (K993106), VLP Mini-Mod (K152976), Compression Hip Screw (CHS) (K993289), CONQUEST FN (K193029), and cannulated screws (K133662)

Device Description

The purpose of this Traditional 510(k) is to add the MR safety information to the labeling, and update the information within the package insert for the Smith & Nephew Plates and Screws Systems: EVOS, Peri-Loc, D-Rad, TC-100, VLP Mini-Mod, Compression Hip Screw (CHS), CONQUEST FN, and cannulated screws. The technological characteristics, function of the devices, packaging and sterilization remain unchanged.

No modification has been made to the device design, material, sterilization and the manufacturing processes of the previously cleared devices.

Indication for Use

Indications for use of the Smith & Nephew, Inc. Plates and Screws are the following:

Compression Hip Screw (CHS)

Adult Indications

1. Intracapsular fractures of the femoral neck. (For high subcapsular fractures it may be more prudent to select a prosthesis in lieu of internal fixation to reduce the risk of a nonunion or avascular necrosis of the femoral head.)
2. Trochanteric or subtrochanteric fractures with appropriate additional postoperative precautions about weight bearing and more than sedentary activity.
3. Osteotomies for patients with diseases or deformities of the hip.
4. Hip arthrodesis.
5. Supracondylar fractures and distal femoral fractures using a supracondylar plate.
6. Ipsilateral femoral shaft/neck fractures.

Pediatric Indications

1. Congenital coxa vara.
2. Congenital dislocation of the hip.
3. Subluxation or dislocation secondary to neurologic disorders such as cerebral palsy, myelomenigocele, poliomyelitis, etc. Usually valgus-anteversion deformities.
4. Coxa plana (Legg-Calve-Perthes disease) for containment of the head completely within the acetabulum.

CONQUEST FN

CONQUEST FN is indicated for displaced and undisplaced intracapsular femoral neck fractures.

D-Rad

The D-RAD SMART PACK System is intended for the fixation of fractures involving the distal radius.

EVOS

The EVOS MINI Plating System is indicated for adolescent (12–18 years) and transitional adolescent (18–21 years) subpopulations and adults, as well as patients with osteopenic bone.

The EVOS MINI Plating System is indicated for fracture fixation, arthrodesis, reconstruction, replantation or reduction of small bones and small bone fragments. This system is also indicated for non-load bearing stabilization and reduction of bone fragments in long bones.

The EVOS Small Fragment Plating System is indicated for adult and adolescent (greater than 12-21 years of age) patients, as well as patients with osteopenic bone. It is indicated for fixation of small and long bone fractures, including, but not limited to, those of the tibia, fibula, femur, humerus, ulna, radius, pelvis, acetabulum, metacarpals, metatarsals, and clavicle.

The EVOS Partial Articular and Anti-Glide Plates are indicated for the treatment of partial articular fractures of the distal and proximal tibia (AO/OTA Fracture Classifications Type B), and for fracture fixation of the fibula.

The EVOS Wrist Fracture Plating System is indicated for adult and pediatric patients, as well as patients with osteopenic bone. It is indicated for fixation of fractures, malunions, and osteotomies involving the radius and ulna.

PERI-LOC

The PERI-LOC Plate and Screw System can be used for adult and pediatric patients, as well as patients with osteopenic bone. PERI-LOC bone plates and bone screws are indicated for fixation of pelvic, small and long bone fractures, including those of the tibia, fibula, femur, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, radius, calcaneus, and clavicle.

PERI-LOC Periarticular Locked Plating System VLP Plates and Screws can be used for adult and pediatric patients, as well as patients with osteopenic bone. PERI-LOC contoured VLP Plates and Screws are indicated for partial articular fractures (AO/OTA Fracture Classification Type B) of the distal and proximal tibia, and for fracture fixation of the fibula. PERI-LOC VLP One-Third Tubular Locking Plates are indicated for, but not limited to, fixation of fractures, non-unions and osteotomies of the medial malleolus, fibula, distal ulna, olecranon, calcaneus and metatarsals.

PERI-LOC Periarticular Locked Plating System Proximal Femur Bone Plates, Bone Screws and Cable Accessories can be used for adult patients as well as patients with osteopenic bone. PERI-LOC Proximal Femur Bone Plates, Bone Screws and Cable Accessories are indicated for fractures of the trochanteric region including simple intertrochanteric, reverse oblique trochanteric, transverse trochanteric, complex multi-fragmentary, and fractures with medial cortex instability; proximal femur fractures combined with ipsilateral shaft fractures; pathological fractures of the proximal femur including metastatic fractures; proximal femur osteotomies; fixation of fractures in osteopenic bone; fixation of nonunions and malunions; basi/transcervical femoral neck fractures; subcapital femoral neck fractures; and subtrochanteric femur fractures.

The Smith & Nephew VLP FOOT Plating System can be used in adolescent (12-18 years) and transitional adolescent (18-21 years) subpopulations and adults, as well as patients with osteopenic bone. The VLP FOOT Plating System is indicated for fracture fixation, reconstruction or arthrodeses of small bones, including those in the forefoot, midfoot and hindfoot.

The Smith & Nephew PERI-LOC Ankle Fusion Plating System can be used in adolescent (12-18 years) and transitional adolescent (18-21 years) subpopulations and adults, as well as patients with osteopenic bone. The PERI-LOC Ankle Fusion Plating System is indicated for ankle arthrodesis and fractures, including the distal tibia, talus and calcaneus.

The VLP MINI-MOD Small Bone Plating System and VLP MINI-MOD Talus Plates are indicated for adolescent (12–18 years) and transitional adolescent (18–21 years) subpopulations and adults, as well as patients with osteopenic bone.

The VLP MINI-MOD Small Bone Plating System is indicated for fracture fixation, arthrodesis, reconstruction, replantation or reduction of small bones and small bone fragments. This system is also indicated for non-load bearing stabilization and reduction of bone fragments in long bones.

The VLP MINI-MOD Talus Plates are indicated for fracture fixation, reconstruction or arthrodesis of small bones, including those in the forefoot, midfoot and hindfoot.

The VLP Wrist Fracture System Radial Plates are indicated for fixation of fractures, malunions, and osteotomies involving the radius.

TC-100

Bone plates and screws from the Smith & Nephew Bone Plate System are used for adult and pediatric patients as indicated for pelvic, small, and long bone fracture fixation. Indications for use include fractures of the tibia, fibula, femoral condyle, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, middle hand and middle foot bones; treatment of the calcaneus; hip arthrodesis, and provisional hole fixation.

Cannulated Screws

Bone plates and screws from the Smith & Nephew Bone Plate System are used for adult and pediatric patients as indicated for pelvic, small, and long bone fracture fixation. Indications for use include fractures of the tibia, fibula, femoral condyle, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, middle hand and middle foot bones; treatment of the calcaneus; hip arthrodesis, and provisional hole fixation.

The 4.0mm Cannulated Screws and associated washers are additionally intended for arthrodesis and osteotomies of small bones and small joints, including scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, patella, ulnar styloid, capitellum, radial head and radial styloid.

The 5.5mm, 6.5mm, 7.0mm, and 8.0mm Cannulated Screws and associated washers are additionally intended for reconstruction, osteotomy, and arthrodesis of various bones and bone fragments appropriate for the size of the device including joint fusions (arthrodesis) in the foot and ankle.

The Smith & Nephew 2.5mm, 3.0mm Cannulated and 3.0mm Headless Compression Screws are intended for fixation of intraarticular and extra-articular fractures and non-unions of small bones and small bone fragments; arthrodeses of small joints; bunionectomies and osteotomies; scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, patella, ulnar styloid, capitellum, radial head and radial styloid.

The Smith & Nephew 2.0mm QFX Screw is indicated for osteotomies of the lesser metatarsals, such as Weil osteotomies. Osteotomies, fusions and fractures of the phalanges, metacarpals and carpals of the hand.

Technological Characteristics
The device design and material of the subject device are same as the predicate Smith & Nephew Plates and Screws Systems: EVOS, Peri-Loc, D-Rad, TC-100, VLP Mini-Mod, Compression Hip Screw (CHS), CONQUEST FN, and cannulated screws cleared under the premarket notifications listed in the tables below.

Performance Data
Below listed Magnetic resonance imaging (MRI) compatibility testing were conducted as per the FDA's guidance "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment", December 11, 2014 and the standards listed below:

1. Magnetically induced displacement force (ASTM F2052)
2. Magnetically induced torque (ASTM F2213)
3. Radiofrequency (RF) induced heating (ASTM F2182)
4. MR image artifact (ASTM F2119)

Substantial Equivalence Information
The Smith & Nephew Plates and Screws Systems are identical in function, design features, materials, sterilization, manufacturing methods and operational principles to the commercially available predicate devices listed in the tables below.

Table 5.1: Substantially Equivalent Predicates to the Compression Hip Screw (CHS) System

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Smith & Nephew Compression Hip Screw (CHS)	K952697 K954712 K993289	09/12/1995 10/31/1995 12/20/1999

Table 5.2: Substantially Equivalent Predicates to the CONQUEST FN System

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Smith & Nephew CONQUEST FN System	K152686 K172785 K193029	03/17/2016 12/22/2017 02/28/2020

Table 5.3: Substantially Equivalent Predicates to the External Fixation Systems

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	D-Rad Plating System	K132296 K161665	01/07/2014 11/15/2016

Table 5.4: Substantially Equivalent Predicates to the EVOS Plating System

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	EVOS Plating System	K140814 K162078 K170457 K170887 K173293 K181533	05/07/2014 11/18/2016 06/14/2017 04/24/2017 01/08/2018 08/09/2018

		K190253 K201527	03/11/2019 07/22/2020

Table 5.5: Substantially Equivalent Predicates to the subject Systems

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Peri-Loc Periarticular and Variable-Angled Locked Plating (VLP) Systems	K033669 K051735 K061352 K062216 K071563 K072818 K080434 K082516 K083032 K090675 K092015 K100325 K110670 K120667 K132886 K143050 K152976	12/10/2003 07/19/2005 06/08/2006 09/15/2006 08/08/2007 11/19/2007 04/10/2008 09/17/2008 01/07/2009 06/04/2009 07/30/2009 05/04/2010 07/12/2011 04/04/2012 02/04/2014 12/18/2014 11/12/2015

Table 5.6: Substantially Equivalent Predicates to the TC-100 Screw and Plating System

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	TC-100 Screw and Plating System	K123055 K993106	01/25/2013 12/09/1999

Table 5.7: Substantially Equivalent Predicates to the Cannulated Screws

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Cannulated Screws	K060736 K111994 K133662	04/18/2006 10/11/2011 5/15/2014

Conclusion

In summary, the only differences between the subject devices and what was previously cleared are the addition of MR safety information to the labeling, the indications and the information within the package insert. The Smith & Nephew Plates and Screws Systems are identical in function, design features, materials, sterilization, manufacturing methods and operational principles to what was previously cleared. Therefore, it is concluded that the Smith & Nephew Plates and Screws Systems are substantially equivalent to the predicate devices.