Dear Mr. Heckaman:

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
Device Name
Zimmer Knee Joint Replacement Prostheses MR Labeling - NexGen® CR, PS, CRA, LPS and LCCK Knee

Indications for Use (Describe)
This device is indicated for patients with severe knee pain and disability due to:
- Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
- Collagen disorders, and/or avascular necrosis of the femoral condyle
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy.
- Moderate valgus, varus, or flexion deformities.
- The salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery.

CR and LPS porous coated femoral and tibial baseplate components may be used cemented or uncemented (biological fixation). The CR Hydroxyapatite/tricalcium phosphate [HA/TCP] coated femoral or tibial baseplate components may only be used uncemented. All other femoral, tibial baseplate and all-polyethylene patella components are indicated for cemented use only.

NexGen Augments that may be used with cemented CR, CRA, PS, LPS, and LCCK femoral and tibial baseplate components are indicated for cemented use only.

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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- Paperwork Reduction Act (PRA) Staff

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Zimmer Knee Joint Replacement Prostheses MR Labeling - NexGen® All-Polyethylene Patella

This device is indicated for patients with severe knee pain and disability due to:
- Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
- Collagen disorders, and/or avascular necrosis of the femoral condyle.
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy
- Moderate valgus, varus, or flexion deformities.
- The salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery.

This device is indicated for cemented use only.
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Zimmer Knee Joint Replacement Prostheses MR Labeling - NexGen® Tibial Components/Modular Tibial Plates

Indications for Use

This device is indicated for patients with severe knee pain and disability due to:
- Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
- Collagen disorders, and/or avascular necrosis of the femoral condyle.
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy.
- Moderate varus, valgus, or flexion deformities.
- The salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery.

NexGen TM Tibial Trays may be used with or without bone cement (biological fixation). NexGen MIS Tibial Plates and Keels are intended for cemented use only.

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

Device Name
Zimmer Knee Joint Replacement Prostheses MR Labeling - NexGen® CR-Flex and LPS-Flex Fixed Bearing Knee

Indications for Use (Describe)
This device is indicated for patients with severe knee pain and disability due to:
- Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
- Collagen disorders, and/or avascular necrosis of the femoral condyle.
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy
- Moderate valgus, varus, or flexion deformities.
- The salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery.

CR-Flex and LPS-Flex porous coated femoral and tibial baseplate components may be used cemented or uncemented (biological fixation). CR-Flex HA/TCP porous coated femoral and tibial baseplate components may only be used uncemented. All other femoral, tibial baseplate and all-polyethylene patella components are indicated for cemented use only.

Specific uses with CR-Flex or LPS-Flex femorals:
- Provides increased flexion capability for patients who have both the flexibility and desire to increase their flexion range.
- The CR-Flex femoral, when used with 90-prefix NexGen CR articular surfaces, 00-prefix 10, 12 or 14 mm or 90-prefix 17 or 20 mm Prolong® Highly Crosslinked Polyethylene CR articular surfaces, is designed for use with a functional posterior cruciate ligament and when load bearing range of motion (ROM) is expected to be less than or equal to 155 degrees.
- The LPS-Flex femoral, when used with the LPS-Flex articular surfaces, is designed for use with both cruciate ligaments excised and when load bearing ROM is expected to be less than or equal to 155 degrees.

Specific Uses with NexGen LPS or LCCK femorals:
- The LPS femoral is designed for use with both cruciate ligaments excised and when load bearing ROM is expected to be less than or equal to 130 degrees.
- The usage of the LCCK femoral is the same as the LPS with the exception that femoral bone loss can be accommodated by femoral stem extensions and augmentation. No varus/valgus constraint or other stability other than that provided by the NexGen LPS is provided when the LCCK femoral component is used with the LPS-Flex articular surfaces.

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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Device Name
Zimmer Knee Joint Replacement Prostheses MR Labeling - NexGen® CR-Flex and LPS-Flex Gender Solutions Female (GSF)

Indications for Use (Describe)
This device is indicated for patients with severe knee pain and disability due to:
- Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
- Collagen disorders, and/or avascular necrosis of the femoral condyle.
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy.
- Moderate valgus, varus, or flexion deformities.
- The salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery.

The CR-Flex GSF and LPS-Flex GSF uncoated (Option) and precoat styles are intended for cemented use only.

The CR-Flex GSF and LPS-Flex GSF porous coated femoral components may be used cemented or uncemented (biological fixation).

Specific uses with CR-Flex GSF or LPS-Flex GSF femorals:
- Provides increased flexion capability for patients who have both the flexibility and desire to increase their flexion range.
- The CR-Flex GSF femoral, when used with 90-prefix NexGen CR articular surfaces, 00-prefix 10, 12 or 14 mm or 90-prefix 17 or 20 mm Prolong® Highly Crosslinked Polyethylene CR articular surfaces, or with Gender Solutions Natural-Knee Flex Congruent articular surfaces, is designed for use with a functional posterior cruciate ligament and when load bearing range of motion (ROM) is expected to be less than or equal to 155 degrees.
- The LPS-Flex GSF femoral, when used with LPS-Flex articular surfaces, is designed for use with both cruciate ligaments excised and when load bearing ROM is expected to be less than or equal to 155 degrees.

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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Device Name
Zimmer Knee Joint Replacement Prostheses MR Labeling - Zimmer Gender Solutions Patello-Femoral Joint (PFJ)

Indications for Use (Describe)
- Osteoarthritis, traumatic arthritis, polyarthritis, and/or severe chondrocalcinosis of the patellofemoral joint.
- The salvage of previously failed surgical attempts (e.g., arthroscopy, lateral release, cartilage transplantation).
- History of patellar dislocation or patella fracture.
- Dysplasia-induced degeneration.

This device is intended for cemented use only.
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Zimmer Knee Joint Replacement Prostheses MR Labeling - NexGen® Rotating Hinge Knee

Indications for Use (Describe)
This device is indicated for patients with:
- Moderate to severe knee instability.
- Significant bone loss and/or ligament deficiencies caused by neoplasms, trauma, rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, and/or avascular necrosis of the femoral condyle.
- Valgus, varus, or flexion deformities.
- The salvage of previously failed surgical attempts.

This device is intended for cemented use only.

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

Device Name
Zimmer Knee Joint Replacement Prostheses MR Labeling - Natural-Knee System

Indications for Use (Describe)
The Natural-Knee System with Cancellous-Structured Titanium (CSTi) Porous Coating is indicated for uncemented or cemented use in skeletally mature individuals with intact medial and lateral collateral ligaments undergoing primary surgery for rehabilitating knees damaged as a result of Noninflammatory Degenerative Joint Disease (NIDJD) or Inflammatory Joint Disease (IJD).

The Natural-Knee primary components without CSTi Porous Coating and all revision components are indicated for cemented use only in skeletally mature individuals with conditions of Noninflammatory Degenerative Joint Disease (NIDJD) or Inflammatory Joint Disease (IJD), correctable valgus-varus deformity and moderate flexion contracture, or failed previous surgery where pain, deformity or dysfunction persists. When the primary components are used, the medial and collateral ligaments must be intact.

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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Zimmer Knee Joint Replacement Prostheses MR Labeling - Natural-Knee II System

Indications for Use (Describe)
The Natural-Knee II System with Cancellous-Structured Titanium (CSTi) Porous Coating is indicated for uncemented or cemented use in skeletally mature individuals with intact medial and lateral collateral ligaments undergoing primary surgery for rehabilitating knees damaged as a result of Noninflammatory Degenerative Joint Disease (NIDJD) or Inflammatory Joint Disease (IJD).

The Natural-Knee II primary components without CSTi Porous Coating, all posterior stabilized and revision components, the N-K II Constrained Knee System, the modular cemented tibial baseplate, and the revision stem and revision fluted stem are indicated for cemented use only in skeletally mature individuals with conditions of Noninflammatory Degenerative Joint Disease (NIDJD) or Inflammatory Joint Disease (IJD), correctable valgus-varus deformity and moderate flexion contracture, or failed previous surgery where pain, deformity or dysfunction persists. When the primary or N-K II Constrained Knee System components are used, the medial and collateral ligaments must be intact.

The Natural-Knee II Durasul polyethylene components are indicated for patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory degenerative joint disease (IJD), e.g., rheumatoid arthritis; correctable valgus-varus deformity and moderate flexion contracture; those patients with failed previous surgery where pain, deformity, or dysfunction persists; and revision of previously failed knee arthroplasty. These devices are intended for cemented use only in the United States.

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

**Device Name**
Zimmer Knee Joint Replacement Prostheses MR Labeling - Natural-Knee®/Natural-Knee® II System Domed All-Poly Patella

**Indications for Use (Describe)**
This device is indicated for:
- Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
- Correctable valgus-varus deformity and moderate flexion contracture.
- Those patients with failed previous surgery where pain, deformity, or dysfunction persists.
- Revision of previously failed knee arthroplasty.

This device is intended for cemented use only.

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

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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**Indications for Use**

**Device Name**
Zimmer Knee Joint Replacement Prostheses MR Labeling - Gender Solutions Natural-Knee® Flex System

**Indications for Use (Describe)**
Components with CSTi porous coating are indicated for uncemented or cemented use in skeletally mature individuals with intact medial and lateral collateral ligaments undergoing primary surgery for rehabilitating knees damaged as a result of Noninflammatory Degenerative Joint Disease (NIDJD) or Inflammatory Joint Disease (IJD).

Components without CSTi porous coating are indicated for cemented use in skeletally mature individuals with intact medial and lateral collateral ligaments with conditions of Noninflammatory Degenerative Joint Disease (NIDJD) or Inflammatory Joint Disease (IJD), correctable varus-valgus deformity and moderate flexion contracture, or failed previous surgery where pain, deformity or dysfunction persists.

The N-K Flex femoral provides increased flexion capability for patients who have both the flexibility and desire to increase their flexion range. When used with N-K Flex, NexGen Trabecular Metal™ CR Monoblock, 90-prefix NexGen CR, 00-prefix 10, 12 or 14mm or 90-prefix 17 or 20mm Prolong® Highly Crosslinked Polyethylene CR articular surfaces, it is designed for use when load bearing ROM is expected to be less than or equal to 155 degrees.

**Type of Use (Select one or both, as applicable)**
- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the subject Zimmer Knee Joint Replacement Prostheses MR Labeling 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, ‘Format for Traditional and Abbreviated 510(k)s’, issued on August 12, 2005.

Sponsor: Zimmer, Inc.
P.O. Box 708
Warsaw, IN  46581-0708
Establishment Registration Number: 1822565

Contact Person: Jason Heckaman
Manager, Regulatory Affairs
Telephone: (574-371-8313)
jason.heckaman@zimmerbiomet.com

Date: September 27, 2017

Subject Device: Trade Name: Zimmer Knee Joint Replacement Prostheses MR Labeling
Common Name: Knee Prosthesis

Classification Name:
- JWH – Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer (21 CFR 888.3560)
- MBH – Prosthesis, Knee, Patello/Femorotibial, Semi-Constrained, Uncemented, Porous, Coated, Polymer/Metal/Polymer (21 CFR 888.3565)
- KRO – Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/Polymer (21 CFR 888.3510)
- KRR – Prosthesis, Knee, Patello/Femoral, Semi-Constrained, Cemented, Metal/Polymer (21 CFR 888.3540)

Predicate Device(s):
Zimmer, Inc.
K872379  Install/Burstein II Modular Total Knee
K892800  MG II Porous Total Knee System
K933785  NexGen Knee System
K946150  Cruciate Retaining (Augmentable) and Constrained Condylar Knee
K951185  NexGen Complete Knee Solution 9mm
Articular Surface
K960279 NexGen Complete Knee Solution Legacy
Posterior Stabilized/Constrained Condylar Knee Femoral Components/Articular Surfaces
K963148 NexGen Complete Knee Solution
K991581 NexGen Complete Knee Solution Legacy
Posterior Stabilized; LPS-Flex Fixed Bearing Femoral and Articular Surface
K003910 NexGen Complete Knee Solution Cross-Linked Polyethylene Cruciate Retaining Articular Surface Components
K023211 NexGen Complete Knee Solution Cruciate Retaining-Flex Femoral Components
K031061 NexGen Porous, Uncemented Femoral and Tibial Baseplate Components
K041100 NexGen Porous HA/TCP Uncemented Femoral and Tibial Baseplate Components
K043101 NexGen Complete Knee Solution MIS Tibial Components Locking Screw and Stem Extensions
K042271 NexGen Complete Knee Solution LPS-Flex Prolong Highly Cross-linked Polyethylene Articular Surfaces
K052879 NexGen Complete Knee Solution MIS Modular Tibial Plates and Keels
K060370 NexGen Knee Gender Solutions Female (GSF) Femoral Components
K062768 NexGen Complete Knee Solution Legacy Posterior Stabilized Flex Fixed Bearing and Titanium Ti-6AL-4V Alloy Femoral
K072160 NexGen Trabecular Metal Tibial Tray
K072281 NexGen Prolong All Poly Patella
K072619 NexGen Complete Knee Solution LPS-Flex Gender Solutions Female Porous Femoral Components
K070695 Zimmer Patella Femoral Joint Prosthesis
K013385 NexGen Complete Knee Solution Rotating Hinge Knee
K152494 Zimmer NexGen Complete Knee Solution Tibial and Femoral Augments
K931651 Natural-Knee Congruent Tibial Insert with Screw
K935789 Posterior Stabilized Apollo Knee System
K936159 Natural-Knee II System
K970498 Natural-Knee II Revision Femoral Spacer
Summary of Technological Characteristics:

The purpose of this submission is the addition of MR Conditional labeling to the Instructions for Use for the predicate devices. The addition of MR labeling to the subject devices does not impact indications, materials, design features or dimensions, packaging or sterilization. The subject devices are intended for use in knee arthroplasty. Specific indications for use are below.
Indications for Use:

**NexGen® CR, PS, CRA, LPS and LCCK Knee**
This device is indicated for patients with severe knee pain and disability due to:
- Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
- Collagen disorders, and/or avascular necrosis of the femoral condyle.
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy.
- Moderate valgus, varus, or flexion deformities.
- The salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery.

CR and LPS porous coated femoral and tibial baseplate components may be used cemented or uncemented (biological fixation). The CR Hydroxyapatite/tricalcium phosphate [HA/TCP] coated femoral or tibial baseplate components may only be used uncemented. All other femoral, tibial baseplate and all-polyethylene patella components are indicated for cemented use only.

NexGen Augments that may be used with cemented CR, CRA, PS, LPS, and LCCK femoral and tibial baseplate components are indicated for cemented use only.

**NexGen® All-Polyethylene Patella**
This device is indicated for patients with severe knee pain and disability due to:
- Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
- Collagen disorders, and/or avascular necrosis of the femoral condyle.
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy
- Moderate valgus, varus, or flexion deformities.
- The salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery.

This device is indicated for cemented use only.

**NexGen® Tibial Components/Modular Tibial Plates**
This device is indicated for patients with severe knee pain and disability due to:
- Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
- Collagen disorders, and/or avascular necrosis of the femoral condyle.
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy.
- Moderate valgus, varus, or flexion deformities.
- The salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery.

NexGen TM Tibial Trays may be used with or without bone cement (biological fixation). NexGen MIS Tibial Plates and Keels are intended for cemented use only.
**NexGen® CR-Flex and LPS-Flex Fixed Bearing Knee**

This device is indicated for patients with severe knee pain and disability due to:
- Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
- Collagen disorders, and/or avascular necrosis of the femoral condyle.
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy
- Moderate valgus, varus, or flexion deformities.
- The salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery.

CR-Flex and LPS-Flex porous coated femoral and tibial baseplate components may be used cemented or uncemented (biological fixation). CR-Flex HA/TCP porous coated femoral and tibial baseplate components may only be used uncemented. All other femoral, tibial baseplate and all-polyethylene patella components are indicated for cemented use only.

Specific uses with CR-Flex or LPS-Flex femorals:
- Provides increased flexion capability for patients who have both the flexibility and desire to increase their flexion range.
- The CR-Flex femoral, when used with 90-prefix NexGen CR articular surfaces, 00-prefix 10, 12 or 14 mm or 90-prefix 17 or 20 mm Prolong® Highly Crosslinked Polyethylene CR articular surfaces, is designed for use with a functional posterior cruciate ligament and when load bearing range of motion (ROM) is expected to be less than or equal to 155 degrees.
- The LPS-Flex femoral, when used with the LPS-Flex articular surfaces, is designed for use with both cruciate ligaments excised and when load bearing ROM is expected to be less than or equal to 155 degrees.

Specific Uses with NexGen LPS or LCCK femorals:
- The LPS femoral is designed for use with both cruciate ligaments excised and when load bearing ROM is expected to be less than or equal to 130 degrees.
- The usage of the LCCK femoral is the same as the LPS with the exception that femoral bone loss can be accommodated by femoral stem extensions and augmentation. No varus/valgus constraint or other stability other than that provided by the NexGen LPS is provided when the LCCK femoral component is used with the LPS-Flex articular surfaces.

**NexGen® CR-Flex and LPS-Flex Gender Solutions Female (GSF), Knee Femoral Components**

This device is indicated for patients with severe knee pain and disability due to:
- Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
- Collagen disorders, and/or avascular necrosis of the femoral condyle.
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy.
- Moderate valgus, varus, or flexion deformities.
- The salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery.

The CR·Flex GSF and LPS·Flex GSF uncoated (Option) and precoat styles are intended for cemented use only.

The CR·Flex GSF and LPS·Flex GSF porous coated femoral components may be used cemented or uncemented (biological fixation).

Specific uses with CR·Flex GSF or LPS·Flex GSF femorals:
- Provides increased flexion capability for patients who have both the flexibility and desire to increase their flexion range.
- The CR·Flex GSF femoral, when used with 90-prefix NexGen CR articular surfaces, 00-prefix 10, 12 or 14 mm or 90-prefix 17 or 20 mm Prolong® Highly Crosslinked Polyethylene CR articular surfaces, or with Gender Solutions Natural-Knee Flex Congruent articular surfaces, is designed for use with a functional posterior cruciate ligament and when load bearing range of motion (ROM) is expected to be less than or equal to 155 degrees.
- The LPS·Flex GSF femoral, when used with LPS·Flex articular surfaces, is designed for use with both cruciate ligaments excised and when load bearing ROM is expected to be less than or equal to 155 degrees.

**Zimmer Gender Solutions Patello-Femoral Joint (PFJ)**
- Osteoarthritis, traumatic arthritis, polyarthritis, and/or severe chondrocalcinosis of the patellofemoral joint.
- The salvage of previously failed surgical attempts (e.g., arthroscopy, lateral release, cartilage transplantation).
- History of patellar dislocation or patella fracture.
- Dysplasia-induced degeneration.

This device is intended for cemented use only.

**NexGen® Rotating Hinge Knee**
This device is indicated for patients with:
- Moderate to severe knee instability.
- Significant bone loss and/or ligament deficiencies caused by neoplasms, trauma, rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, and/or avascular necrosis of the femoral condyle.
- Valgus, varus, or flexion deformities.
- The salvage of previously failed surgical attempts.

This device is intended for cemented use only.

**Natural-Knee System**
The Natural-Knee System with Cancellous-Structured Titanium (CSTi) Porous Coating is indicated for uncemented or cemented use in skeletally mature individuals with intact medial and
lateral collateral ligaments undergoing primary surgery for rehabilitating knees damaged as a result of Noninflammatory Degenerative Joint Disease (NIDJD) or Inflammatory Joint Disease (IJD).

The Natural-Knee primary components without CSTi Porous Coating and all revision components are indicated for cemented use only in skeletally mature individuals with conditions of Noninflammatory Degenerative Joint Disease (NIDJD) or Inflammatory Joint Disease (IJD), correctable valgus-varus deformity and moderate flexion contracture, or failed previous surgery where pain, deformity or dysfunction persists. When the primary components are used, the medial and collateral ligaments must be intact.

**Natural-Knee II System**

The Natural-Knee II System with Cancellous-Structured Titanium (CSTi) Porous Coating is indicated for uncemented or cemented use in skeletally mature individuals with intact medial and lateral collateral ligaments undergoing primary surgery for rehabilitating knees damaged as a result of Noninflammatory Degenerative Joint Disease (NIDJD) or Inflammatory Joint Disease (IJD).

The Natural-Knee II primary components without CSTi Porous Coating, all posterior stabilized and revision components, the N-K II Constrained Knee System, the modular cemented tibial baseplate, and the revision stem and revision fluted stem are indicated for cemented use only in skeletally mature individuals with conditions of Noninflammatory Degenerative Joint Disease (NIDJD) or Inflammatory Joint Disease (IJD), correctable valgus-varus deformity and moderate flexion contracture, or failed previous surgery where pain, deformity or dysfunction persists. When the primary or N-K II Constrained Knee System components are used, the medial and collateral ligaments must be intact.

The Natural-Knee II Durasul polyethylene components are indicated for patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory degenerative joint disease (IJD), e.g., rheumatoid arthritis; correctable valgus-varus deformity and moderate flexion contracture; those patients with failed previous surgery where pain, deformity, or dysfunction persists; and revision of previously failed knee arthroplasty. These devices are intended for cemented use only in the United States.

**Natural-Knee®/Natural-Knee® II System Domed All-Poly Patella**

This device is indicated for:
- Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
- Correctable valgus-varus deformity and moderate flexion contracture.
- Those patients with failed previous surgery where pain, deformity, or dysfunction persists.
- Revision of previously failed knee arthroplasty.

This device is intended for cemented use only.
**Gender Solutions Natural-Knee® Flex System**

Components with CSTi porous coating are indicated for uncemented or cemented use in skeletally mature individuals with intact medial and lateral collateral ligaments undergoing primary surgery for rehabilitating knees damaged as a result of Noninflammatory Degenerative Joint Disease (NIDJD) or Inflammatory Joint Disease (IJD).

Components without CSTi porous coating are indicated for cemented use in skeletally mature individuals with intact medial and lateral collateral ligaments with conditions of Noninflammatory Degenerative Joint Disease (NIDJD) or Inflammatory Joint Disease (IJD), correctable varus-valgus deformity and moderate flexion contracture, or failed previous surgery where pain, deformity or dysfunction persists.

The N-K Flex femoral provides increased flexion capability for patients who have both the flexibility and desire to increase their flexion range. When used with N-K Flex, NexGen CR-Flex Mobile*, NexGen UC-Flex Mobile*, NexGen Trabecular Metal™ CR Monoblock, 90-prefix NexGen CR, 00-prefix 10, 12 or 14mm or 90-prefix 17 or 20mm Prolong® Highly Crosslinked Polyethylene CR articular surfaces, it is designed for use when load bearing ROM is expected to be less than or equal to 155 degrees.

**Summary of Performance Data**

- **Non-Clinical Tests:**
  
  Zimmer has performed non-clinical Magnetic Resonance Imaging (MRI) studies on implants which are determined to be MR Conditional in accordance to ASTM F2503-13 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. MR Tests included the following:
  
  - RF-induced heating (ASTM F2182-11a)
  - Image Artifact (ASTM F2119-07)
  - Magnetic Displacement (ASTM 2052-14)

  Testing has been performed to establish product non-pyrogenicity.

- **Clinical Tests:**
  
  Clinical data was not provided for the subject devices.

**Substantial Equivalence Conclusion**

Non-clinical tests provided in this Traditional 510(k) establish the conditional safety and compatibility of the passive implants in a magnetic resonance (MR) environment. The subject devices are substantially equivalent to the legally marketed predicated devices.