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510(k) Premarket Notification
Summary of Safety and Effectiveness
for the
Natural Hip System

In accordance with the Food and Drug Administration Interim Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21CFR 807, this is to serve as a 510(k) Summary for the components of the Natural Hip System.

Submitter:

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Proprietary name: Natural Hip System

Common Name: Artificial hip component

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Classification name: Prosthesis, Hip, Semi-constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous UnCemented Prosthesis 21CFR 888.3353).

Class III → JM

Predicate Devices: The features employed by the components of the Natural Hip System are substantially equivalent to the features employed by the following legally marketed predicate devices:

- Premier Total Hip Stem: Intermedics Orthopaedics Inc. (510(k) #K894051).
- Osteonics ODC Cemented Hip Stem: Osteonics Corporation (510(k) number unknown to IOI).
- Osteonics ODC Hip Stem: Osteonics Corporation (510(k)nown to IOI).
- PFC Cemented Hip Stem: Johnson & Johnson Orthopaedics (510(k) number unknown to IOI).

- Perfecta IMC Stem: Orthomet Inc. (510(k) number unknown to IOI).

Device Description:

The components of the Natural Hip System employ an IOI 12/14 Morse Taper configured trunnion, available in either threaded or smooth (non-threaded) configuration, for the attachment of the IOI's femoral bearing heads, including the zirconia bearing heads. The IOI 12/14 Morse Taper configured trunnion has previously been determined substantially equivalent by the FDA via the 510(k) #K913060. In addition, the use of zirconia bearing heads with the IOI 12/14 Morse Taper configured trunnion have also previously been determined substantially equivalent by the FDA via 510(k) #s' K942330 and K942406. Please note that the components of the Natural Hip System with a smooth Morse Taper configured trunnion are not intended to be used with the ceramic bearing heads. Such a warning will be clearly stated on the IOI package insert accompanying the component of the Natural Hip System (See IOI's proposed package insert provided in Appendix A of this 510(k) premarket notification submission).

The components of the Natural Hip System are available with and without a proximal collar. The proximal collar enhances cement pressurization in a cemented total hip arthroplasty. The components of the Natural Hip System incorporate a wedged shaped geometry on the proximal area of the hip stem for enhanced fit of the device in a prepared femoral canal. The wedge shaped geometry is designed to reduce stresses that can potentially cause cement/bone or bone/prosthesis interface breakdown. The components of the Natural Hip System are available with or without normalizations in the proximal anterior and posterior regions of the hip stem. Normalizations are series of steps and walls which potentially reduce subsidence and medial migration. In

addition, the proximal region of the components of the Natural Hip System are available with or without proximal polymethylmethacryalte (PMMA) spacers which provide an even cement mantle in a cemented total hip arthroplasty.

Surface enhancement via grit blasting is employed on either the proximal third or the entire length of the hip stem below the collar of the components of the Natural Hip System. Grit blasted surfaces provide enhanced fixation in both cemented and cementless total hip arthroplasties. The grit blasted surfaces provide a surface roughness of 63-149μ-inches. In a cemented application, the grit blasted surface provides greater cement interdigitation with bone cement. In a press-fit or cementless application, the grit blasted surfaces provide an enhanced bone/prosthesis interface.

The distal portion of the components of the Natural Hip System employs a hole for the attachment of a distal centralizer fabricated from UHMWPe. The distal centralizer has been previously determined substantially equivalent by the FDA via 510(k) #K913208.

The components of the Natural Hip System are available in 9 sizes (sizes 00 through 7).

Intended Use:

The components of the Natural Hip System, like the predicate IOI and competitive devices, are intended for cemented application. In addition, the components of the Natural Hip System are intended for cementless application.

The Indications for Use for the components of the Natural Hip System are as follows:

1. Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.

2. Those patients with failed previous surgery where pain, deformity, or dysfunction persists.

3. Revision of previously failed arthroplasty.

Total hip replacements may be considered for younger patients if any unequivocal indication outweighs the risks associated with the age of the patient (see "Warnings and Precautions"), and modified demands regarding activity and hip joint loading are assured. This includes severely crippled patients with multiple joint involvement, for whom an immediate need of hip mobility leads to an expectation of significant improvement in the quality of their lives.

Summary of Technological Characteristics:

The features of the components of the Natural Hip System are substantially equivalent to the aforementioned predicate IOI and/or competitive devices in terms of materials, intended use and design characteristics. A comparison of the features of the components of the Natural Hip System in terms of materials, intended use and design characteristics to the aforementioned legally marketed predicate devices is as follows:

Materials:
Substantial equivalence in terms of materials is based upon the fact that both the subject devices and the legally marketed predicate devices are fabricated from either cobalt chromium alloy or titanium alloy.

Intended Use:
The components of the Natural Hip System, like the predicate IOI and competitive devices, are intended for cemented application. The components of the Natural Hip System differ from the legally marketed predicate devices in that they are also intended for cementless application. The subject devices and the predicate devices share the same indications for use. Therefore, in terms of intended use the components of the Natural Hip System are substantially equivalent to the legally marketed predicate devices.

Design characteristics:
The design characteristics of the components of the Natural Hip System are substantially equivalent to the predicate devices based upon the following;

- The components of the Natural Hip System like the aforementioned legally marketed predicate devices incorporate a wedged shaped geometry on the proximal area of the hip stem for enhanced fit in a prepared femoral canal.

- The components of the Natural Hip System like the predicate IOI's Premier Total Hip stem and Orthomet's Perfecta IMC Stem are available with the optional normalizations on the proximal third of the femoral stem

- The components of the Natural Hip System like the predicate Osteonics' ODC Hip Stem and the ODC Fx Hip Stem are available without the optional normalizations on the proximal third of the femoral stem

- The components of the Natural Hip System like the aforementioned legally marketed predicate devices are available with proximal collar.

Please note that the components of the Natural Hip System are also available, as an option to the surgeon, without the proximal collar.

- The components of the Natural Hip System like the predicate legally marketed IOI's Premier Total Hip Stem, Osteonics' ODC Hip Stem, Johnson & Johnson's PFC Cemented Hip Stem, and the Orthomet's Perfecta IMC Stem are available with the distal PMMA centralizer.

- The components of the Natural Hip System like the predicate legally marketed predicate IOI's Premier Total Hip Stem, Osteonics ODC Hip Stem, Johnson & Johnson's PFC Cemented Hip Stem, and the Orthomet's Perfecta IMC Stem employ grit blasted surface on the proximal third of the femoral stem. In addition, the components of the Natural Hip System, like the predicate Osteonics' ODC Fx Hip Stem, are available as an option with a grit blasted surface along the entire length below the collar of the hip stem.

Therefore, in terms of design characteristics the components of the Natural Hip System are substantially equivalent to the legally marketed predicate devices. Marketing literature on the aforementioned predicate devices is provided in Appendix D of this 510(k) premarket notification submission.

A side by side tabular comparison of the features of the components of the Natural Hip System to those of the predicate devices follows.

Characteristics	Subject Devices	Predicate Devices				
	The components of the Natural Hip System	Premier Total Hip Stem	ODC Fx Hip Stem	ODC Hip Stem	PFC Cemented Hip Stem	Perfecta IMC Stem
Manufacturer	IOI	IOI	Osteonics	Osteonics	J & J	Orthomet
510(k)#	-	K894051	Unknown	Unknown	Unknown	Unknown
Material	~~Cast CoCr~~/ Forged CoCr/ Titanium alloy	Titanium alloy	Cast CoCr	Cast CoCr	CoCr alloy	Forged CoCr alloy
Application	Cemented/ Cementless	Cemented	Cemented	Cemented	Cemented	Cemented
Proximal anterior/posterior normalization.	Available with or without normalizations	Yes	No	No	No	Yes
Proximal wedge shaped design	Yes	Yes	Yes	Yes	Yes	Yes
Proximal PMMA centralizers	Available with or without PMMA centralizers	No	No	No	Yes	No
Distal PMMA centralizers	Yes	Yes	No	Yes	Yes	Yes
Proximal collar	Available with or without collar	Yes	Yes	Yes	Yes	Yes
Surface enhancement via grit blasting	Proximal third or entire length below the collar of the hip stem	Yes, but proximal third only	Yes, hip stem below the collar	Yes, but proximal third only	Yes, but proximal third only	Yes, but proximal third only
neck lengths	25-41mm	35mm	25-35mm	25-40mm	unknown	Unknown
sizes	9 sizes	7 sizes	5 sizes	7 sizes	5 sizes	6 sizes