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

September 3, 2015

Exactech Incorporated
Mr. Thomas McNamara
Regulatory Affairs Specialist
2320 North West 66th Court
Gainesville, Florida 32653

Re: K141960
Trade/Device Name: Exactech® Novation® Crown Cup®
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, LZO, JDI, LWJ, MBL
Dated: July 22, 2015
Received: July 27, 2015

Dear Mr. McNamara:

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" (21CFR 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 yours,

Mark N. Melkerson -S

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

Enclosure

Indications for Use

510(k) Number: K141960

Device Name: Exactech® Novation® Crown Cup®

INDICATIONS

All Exactech Hip Systems are indicated for use in skeletally mature individuals undergoing primary surgery for hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Components of Exactech Hip Systems are also potentially indicated for ankylosing spondylitis, congenital hip dysplasia, revision of failed previous reconstructions where sufficient bone stock is present, and to restore mobility resulting from previous fusion.

- Cemented femoral stems and cemented acetabular cups are intended for cemented fixation only.
- Press-fit femoral stems and acetabular cups are intended for press-fit fixation.
- Femoral heads and endoprostheses are intended for use in cemented and press-fit applications.

Prescription Use___X__	**and/or**	**Over-The-Counter Use_____**
(Part 21 CFR 801 Subpart D)		**(21 CFR 807 Subpart C)**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Exactech® Novation® Crown Cup® Plasma Spray Coating Manufacturing Change Traditional 510(k)

510(k) Summary

Sponsor: Exactech®, Inc
2320 NW 66th Court
Gainesville FL, 32653

Phone: (352) 377-1140
Fax: (352) 378-2617

FDA Establishment Number 1038671

Date: August 27, 2015

Contact Person: Thomas McNamara
Regulatory Affairs Specialist
Telephone: (352) 377-1140
Fax: (352) 378-2617

Proprietary Name: Exactech® Novation® Crown Cup®

Common Name: Acetabular Component

Classification Name:

- Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented, 21 CFR 888.3353, Class II, Product Code LZO
- Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented, 21 CFR 888.3350 Class II, Product Code JDI
- Prosthesis, Hip, Semi-constrained, Meta/Polymer, Porous Uncemented, 21 CFR 888.3358, Class II, Product Code LPH
- Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented, 21 CFR 888.3360, Class II, Product Code LWJ
- Prosthesis, Hip, Semi-Constrained, Uncemented, Metal/Polymer, Porous, 21 CFR 888.3358, Class II, Product Code MBL

Legally Marketed Device to Which Substantial Equivalence Is Claimed:

Name	Manufacturer	510(k) Number
Exactech Novation Crown Cup and Liners	Exactech, Inc	K070479, K100269

Indication for Use:
All Exactech Hip Systems are indicated for use in skeletally mature individuals undergoing primary surgery for hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Components of Exactech Hip Systems are also

Exactech® Novation® Crown Cup® Plasma Spray Coating Manufacturing Change Traditional 510(k)

potentially indicated for ankylosing spondylitis, congenital hip dysplasia, revision of failed previous reconstructions where sufficient bone stock is present, and to restore mobility resulting from previous fusion.

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Device Description

The proposed Novation Crown Cup devices represent a modification to the predicate Novation Crown Cup cleared in K070479 and K100269. Both the predicate and proposed devices have the same intended use, general design features, and basic fundamental scientific technology. The only difference between the predicate and the proposed devices is the process by which the titanium plasma spray coating is applied.

Testing:

The following engineering analyses were conducted to demonstrate substantial equivalence of the proposed Novation Crown Cup devices to the predicate Novation Crown Cups:

- Stereological Evaluation of Porous Coating
- Tensile and Shear Testing of Porous Coating
- Abrasion Resistance Testing

Substantial Equivalence Conclusion:

Results of engineering studies referenced in this 510(k) submission demonstrate the proposed Novation Crown Cup are substantially equivalent to cleared Novation Crown Cup devices.