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

November 3, 2016

Nanova Biomaterials Inc.
Andrew Ritts
Director of Regulatory Affairs
3806 Mojave Ct
Columbia, Missouri 65202

Re: K161174
Trade/Device Name: Nanova Interference Screw
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI
Dated: September 26, 2016
Received: October 4, 2016

Dear Andrew Ritts:

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 yours,

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)*
K161174

Device Name
Nanova Interference Screw

Indications for Use *(Describe)*
Nanova™ Interference Screw is indicated for the fixation of soft tissue grafts or bone-tendon-bone grafts during cruciate ligament reconstruction surgeries of the knee. The 7, 8 and 9mm x 23mm screws are also indicated for: medial and lateral collateral ligament repair of the knee, proximal bicep tenodesis in the shoulder and distal bicep tenodesis in the elbow.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## Section 5. 510(k) Summary

1) Submitted By:

Nanova Biomaterials, Inc
3806 Mojave Ct
Columbia, MO 65202
USA
573-875-6682

Contact Person: Andrew Ritts Phone: (573) 823-3114
Secondary Contact: Richard Lebens Phone: (573) 875-6682

2) Establishment Registration No.: 3011430871

3) Date Prepared: April 19, 2016

4) Device Trade Name: Nanova™ Interference Screw

5) Device Common Name: Interference Screw

6)

| | |
|---|---|
| Device Classification Name/ | Fastener, Fixation, Biodegradable, Soft Tissue/ |
| Product code/ Regulation number: | MAI/ 888.3030 |

7) Classification Panel: Orthopedic

8) Device Class: Class II

9) Predicated Devices:
**Nanova™ Interference Screw** is believed to be substantially equivalent to Biorci® Interference Screw (K032224) and MILAGRO® Interference Screw (K060830).

10) Indication for Use:
**Nanova™ Interference Screw** is indicated for the fixation of soft tissue grafts or bone-tendon-bone grafts during cruciate ligament reconstruction surgeries of the knee. The 7, 8 and 9mm x 23mm screws are also indicated for: medial and lateral collateral ligament repair of the knee, proximal bicep tenodesis in the shoulder and distal bicep tenodesis in the elbow.

NANOVA



**Section 5. 510(k) Summary - Cont.**

11) Device Description:

**Nanova™ Interference Screw** is a cannulated, threaded, tapered fastener for use in interference fixation of soft tissue grafts or bone-tendon-bone grafts. The device is made from a copolymer of absorbable Poly-L/D-lactide (PLDLA) reinforced with hydroxyapatite. **Nanova™ Interference Screws** are single use, prescription, long term implant, no drug.

12) Substantial Equivalence:

The document, "Guidance on the CDRH Premarket Notification Review Program, 6/30/86 (K86-3)" was used to determine substantial equivalence:

a) The applicant device has the same intended use as the 510(k) cleared predicate listed above.

b) The technological characteristics of this product are believed to be substantially equivalent as those for the predicate device. This device and its predicates use similar performance characteristics, manufacturing materials, and design. **Nanova*™* Interference Screw** is packaged in a similar manner to its predicate and many 510k cleared products already on the market. .

**Nanova*™* Interference Screw** has the same Intended Use as the predicate devices to which it was compared, and there are no differences in technological characteristics which raise new questions of safety and / or effectiveness. Therefore, **Nanova*™* Interference Screw** is substantially equivalent.

13) Non-Clinical Performance Testing:

Non-clinical testing was completed to assess its performance. The data provided in this 510(k) submission shows that the composition is safe based on the biocompatibility risk assessment conducted and a benchtop assessment. ISO 10993 was utilized for testing biocompatibility (all testing passed). Mechanical and performance testing was compared with the predicate, which resulted in similar mechanical and performance to the predicate (all testing passed). **Nanova*™* Interference Screw** was evaluated for pyrogens by bacterial endotoxin LAL testing and ISO Materials Mediated Rabbit Pyrogen and determined to be nonpyrogenic.

14) Clinical Performance Testing:

Clinical performance data was not included.

**Conclusion:**

Nanova Biomaterials Inc. believes that **Nanova*TM* Interference Screw** is substantially equivalent to currently legally marketed products. It does not introduce new indications for use, has similar technological characteristics and does not introduce new potential hazards or safety risks.