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

May 5, 2017

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

Re: K163672
Trade/Device Name: Nanova Screw-in Suture Anchor, Nanova Push-in Suture Anchor
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: March 17, 2017
Received: March 27, 2017

Dear Mr. 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,

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)*
K163672

Device Name
Nanova Push-In Suture Anchor

Indications for Use *(Describe)*
Nanova Push-In Suture Anchor is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/ wrist, and elbow in the following procedures

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot reconstruction, Metatarsal Ligament Repair/Tendon Repair, Bunionectomy

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction.

Elbow: Biceps Tendon Reattachment; Tennis Elbow Repair, Ulnar or Radial collateral Ligament Reconstruction, Lateral Epicondylitis Repair

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:

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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)*
K163672

Device Name
Nanova Screw-In Suture Anchor

Indications for Use *(Describe)*
Nanova Screw-In Suture Anchor is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/ wrist, and elbow in the following procedures

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot reconstruction, Metatarsal Ligament Repair/Tendon Repair, Bunionectomy

Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction.

Elbow: Biceps Tendon Reattachment; Tennis Elbow Repair, Ulnar or Radial collateral Ligament Reconstruction, Lateral Epicondylitis Repair

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

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Nanova Biomaterials, Inc.
Nanova Suture Anchor
Fastener, Fixation, Biodegradable, Soft Tissue
K163672

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: December 19, 2016
4) Device Trade Name: Nanova™ Screw-In Suture Anchor
5) Device Common Name: Suture Anchor
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™ Screw-In Suture Anchor is believed to be substantially equivalent to BioComposite Corkscrew (K082810).

Nanova™ Push-In Suture Anchor is believed to be substantially equivalent to BioComposite PushLock (K082810) and Osteoraptor (K151105).

10) Indication for Use:

Nanova™ Screw-In Suture Anchor is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/ wrist, and elbow in the following procedures

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot reconstruction, Metatarsal Ligament Repair/Tendon Repair, Bunionectomy

Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction.

Elbow: Biceps Tendon Reattachment; Tennis Elbow Repair, Ulnar or Radial collateral Ligament Reconstruction, Lateral Epicondylitis Repair

Nanova™ Push-In Suture Anchor is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/ wrist, and elbow in the following procedures

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot reconstruction, Metatarsal Ligament Repair/Tendon Repair, Bunionectomy

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction.

Elbow: Biceps Tendon Reattachment; Tennis Elbow Repair, Ulnar or Radial collateral Ligament Reconstruction, Lateral Epicondylitis Repair

11) Device Description:

The Nanova™ Suture Anchor is comprised of two types: Screw-In and Push-In. **Nanova™ Screw-In Suture Anchor** is a cannulated, threaded, tapered anchor with integral eyelet for suturing soft tissue to bone. **Nanova™ Push-In Suture Anchor** is a cannulated anchor with integral eyelet for suture soft tissue to bone. In addition the Push-In anchor can use a knotless technique by capturing suture. Suture anchors are preloaded with suture on a handled inserter with a hex driver. The device is made from a copolymer of absorbable 70-30 Poly-L/D-lactide (PLDLA) reinforced with hydroxyapatite. **Nanova™ Screw-In Suture Anchors** 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*™* Suture Anchor** is packaged in a similar manner to its predicate and many 510k cleared products already on the market. Benchtop testing shows similar strengths between **Nanova™ Suture Anchor** and the

predicates. Table 1 and 2 compares **Nanova™ Suture Anchors** to their predicates.

Table 1 Technological comparison of **Nanova™ Screw-In Suture Anchor** and BioComposite Corkscrew (K082810).

Name	**Nanova™ Screw-In Suture Anchor**	BioComposite Corkscrew (K082810).
Intended use (same)	Fixation of suture (soft tissue) to bone	Fixation of suture (soft tissue) to bone
Sterility (same)	EtO at 10^{-6} SAL	EtO at 10^{-6} SAL
Configuration/ Dimensions (D=diameter, L=length, S= # of sutures)	4.5 mm D, 15 mm L, 2 S 5.5 mm D, 15 mm L, 3 S 6.5 mm D, 15 mm L, 3 S	4.5 mm D, 15 mm L, 2 S 5.5 mm D, 15 mm L, 2 or 3 S 6.5 mm D, 15 mm L, 2 or 3 S
Packaging (same)	Anchor loaded with suture on driver sealed in Tyvek pouch, which is then sealed in a foil pouch	Anchor loaded with suture on driver sealed in Tyvek pouch, which is then sealed in a foil pouch

Table 2. Technical Comparison of **Nanova™ Push-In Suture Anchor,** Osteoraptor (K151105), and Bio-Composite PushLock (K082810).

Name	**Nanova™ Push-In Suture Anchor**	Osteoraptor (K151105).	Bio-Composite PushLock™ (K082810)
Intended Use	Fixation of suture (soft tissue) to bone	Fixation of suture (soft tissue) to bone	Fixation of suture (soft tissue) to bone
Sterility (same)	EtO at 10^{-6} SAL	EtO at 10^{-6} SAL	EtO at 10^{-6} SAL
Configuration/ Dimensions (D=diameter, L=length, S= # of sutures)	2.5 mm D, 12.6 mm L, 1S 3.5 mm D, 12.6 mm L, 1S 4.5 mm D, 12.6 mm L, 1S	2.3 mm* D, 15 mm L, 1S 2.9 mm* D, 15 mm L, 1S	2.4 mm D, 11.3 mm L, 1S 2.9 mm D, 15.5 mm L, 1S 3.5 mm D, 19.5 mm L, 1S 4.5 mm D, 28 mm L, 1 S
Packaging (same)	Anchor loaded with suture on driver sealed in Tyvek pouch, which is then sealed in a foil pouch	Anchor loaded with suture on driver sealed in foil pouch	Anchor loaded with suture on driver sealed in plastic tray with Tyvek pouch, which is then sealed in a foil pouch

* Osteoraptor size based off hole size, not anchor size

In addition **Nanova™ Suture Anchor** and predicates are made from similar materials, polylactic acid and calcium phosphate composites. Performance strength of **Nanova™ Suture Anchor** is similar to their predicates.

Nanova*™* Suture Anchor 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*™* Suture Anchor** 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™ Screw-In Suture Anchor** was tested by: axial pullout strength, axial fatigue strength, max torque, insertion torque, and immersion pullout strength. **Nanova™ Push-In Suture Anchor** was tested by: axial pullout strength, axial fatigue strength, and immersion pullout strength.

14) Clinical Performance Testing:

Clinical performance data was not included.

Conclusion:

Nanova Biomaterials Inc. believes that **Nanova*™* Suture Anchor** 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.