August 25, 2022

OrthoNovis, Inc.
Ken West
CEO & President
1 Hargrove Grade, 2F
Palm Coast, Florida 32137

Re: K213905
Trade/Device Name: ONX Large External Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: KTT
Dated: July 29, 2022
Received: August 1, 2022

Dear Ken West:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For: Ting Song, Ph.D., R.A.C.
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213905

Device Name
ONX Large External Fixation System

Indications for Use *(Describe)*

- Stabilization/fixation of:
  - Long bone fractures in tibia and femur
  - Fractures of pelvis and ankle
  - Peri-articular and intra-articular fractures of knee and ankle
- Joint arthrodesis
- Non-unions and mal-unions
- Osteotomies

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."

PSC Publishing Services (301) 443-6740 EF

K213905 – 510(K) SUMMARY

Submitter's Name:	OrthoNovis, Inc.
Submitter's Address:	1 Hargrove Grade, 2F Palm Coast, Florida 32137
Submitter's Telephone:	352-807-3306
Contact Person:	Ken West Orthonovis, Inc. 352-807-3306 operations@orthonovis.com
Date Summary was Prepared:	December 13, 2021
Trade or Proprietary Name:	ONX Large External Fixation System
Common or Usual Name:	Large External Fixation System
Classification:	Class II per 21 CFR §888.3030
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories
Product Code:	KTT
Classification Panel:	Orthopedic – Joint Arthroplasty Devices (DHT6A)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The ONX Large External Fixation System is an external fixation device consisting of bone pins, connecting rods, clamps, posts, and related accessories used for the management of bone fractures and reconstructive orthopedic surgery. The device is a modular system designed to provide a broad range of frame construction options. The connecting rods are made from unidirectional carbon fiber reinforced epoxy. Pins, components, and posts are made from materials conforming to ASTM F136 and ASTM F138.

INDICATIONS FOR USE

The ONX Large External Fixation System is indicated for the following:

- Stabilization/fixation of:
  - Long bone fractures in tibia and femur
  - Fractures of pelvis and ankle
  - Peri-articular and intra-articular fractures of knee and ankle
- Joint arthrodesis
- Non-unions and mal-unions
- Osteotomies

TECHNOLOGICAL CHARACTERISTICS

The intended use, design principles, materials and overall dimensions of the subject and predicate devices are substantially the same. Both the subject and predicate devices are intended to stabilize traumatic or surgically created instabilities of the pelvis and lower extremities through the use of implantable pins and external components in a variety of sizes. These components are used to create a rigid construct (frame) suitable to the individual needs of the patient. As with one or more of the predicate devices, the implantable bone pins are made from titanium alloy or stainless steel and are distally threaded or centrally threaded to enable unilateral or bilateral frame construction.

Any differences in the technological characteristics between the subject and predicate devices do not raise new issues of safety or efficacy.

Data is provided to demonstrate substantial equivalence including engineering analysis of the subject and predicate designs.

Overall, ONX Large External Fixation System has the following similarities to the predicate devices:

- Has the same intended use,
- Uses the same operating principle,
- Incorporates the same design,
- Incorporates the same or very similar materials, and
- Has similar packaging and sterilized using the same materials and processes.

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Product Code**	**Predicate Type**
K110965	Renovis T 710 Large External Fixation System	Renovis Surgical Technologies, LLC	KTT	Primary

PERFORMANCE DATA

An engineering analysis has been conducted to evaluate the ONX Large External Fixation System according to ASTM F1541 and construct fatigue testing under axial load per ASTM F1541 Annex 7 has been performed to show that the subject is substantially equivalent to the predicate in mechanical performance.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the ONX Large External Fixation System is substantially equivalent to the predicate device.