August 1, 2025

AIRS Inc.
Sanghyun Joung
CEO
Robot Innovation Center KIRIA 75, Nowon-ru, Buk-gu
Room 202
Daegu, 41496
Korea, South

Re: K250315
Trade/Device Name: Ronavis - Fx (fx-001)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HTY
Dated: May 30, 2025
Received: May 30, 2025

Dear Sanghyun Joung:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tejen D. Soni -S

For
Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250315

Device Name

RONAVIS – FX (FX-001)

Indications for Use *(Describe)*

The RONAVIS-FX is intended to be implanted through the skin so that a pulling force (traction) may be applied to the skeletal system and for temporary bone stabilization (<24 hours) of bone fragments in extremity and orthopedic procedures.

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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"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."

510(k) Summary for RONAVIS-FX

1. Submitter Information:

- **Company Name**: AIRS Inc.
- **Address**: 202, Robot Innovation Center KIRIA, 75, Nowon-ro, Bukgu, Daegu, Republic of Korea
- **Contact Person**: Sanghyun Joung
- **Phone Number**: +82-269-6802 / +82-10-3480-3320
- **Email**: shjoung@airsurgical.net

- **Date Prepared**: June 10, 2025

2. Device Information:

- **Trade Name**: RONAVIS-FX
- **Common Name**: Anchor Pin
- **Classification**: Class II
- **Product Code**: HTY
- **Regulation Number**: 21 CFR 888.3040 (Smooth or Threaded Metallic Bone Fixation Fastener)

3. Predicate Devices:

Device Name	510(k) Number	Manufacturer
Apex Pins (Primary Predicate)	K061493	Stryker Howmedica Osteonics Corp
Synthes (USA) Hydroxyapatite (HA) Coated Schanz Screws	K040701	Synthes (USA)
SMV Scientific K-Wire and Pins	K182171	Summit MedVentures

4. Device Description:

The RONAVIS-FX is an external fixation device configured as a pin, which is inserted into the bone uni-cortically during orthopedic procedures. It consists of three components: a sleeve, an inner pin, and an anchor head. It is made of SUS316L and is provided non-sterilized. It should be sterilized by the user before use and is prohibited from being reused.

5. Indications and Intended Use:

The RONAVIS-FX is intended to be implanted through the skin so that a pulling force (traction) may be applied to the skeletal system and for temporary bone stabilization (<24 hours) of bone fragments in extremity and orthopedic procedures.

6. Substantial Equivalence:

The RONAVIS-FX is substantially equivalent to the predicate device based on:

- Similar technological characteristics and biocompatibility.
- Identical intended use in temporary bone stabilization and correction.
- Comparable material composition (316L stainless steel).

No new issues are raised compared to the predicate device.

7. Performance Testing:

- **Mechanical Testing**: Testing based on **ASTM F543** and **ASTM F1541**, demonstrating adequate torsional strength, axial pull-out strength, and bending strength.
- **Biocompatibility**: Evaluated per **ISO 10993-1**, **10993-5**, **10993-10**, **10993-11** and **10993-23** for cytotoxicity, sensitization, irritation, and systemic toxicity.

8. Conclusion:

Based on materials, performance testing, biocompatibility data, primary use, and comparison to predicate device, the RONAVIS-FX has been shown to be substantially equivalent to legally marketed predicate device.