In2Bones USA, LLC
Christine Scifert
VP of Quality and Regulatory
6000 Poplar Ave, Suite 115
Memphis, Tennessee 38119

December 17, 2021

Re: K212872
Trade/Device Name: Avenger Radial Head System
Regulation Number: 21 CFR 888.3170
Regulation Name: Elbow joint radial (hemi-elbow) polymer prosthesis
Regulatory Class: Class II
Product Code: KWI
Dated: November 1, 2021
Received: November 3, 2021

Dear Christine Scifert:

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 Jiping Chen, Ph.D., M.P.H.
Acting Division 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)*
K212872

Device Name
Avenger Radial Head System

Indications for Use *(Describe)*
The Avenger Radial Head System is intended for replacement of the proximal end of the radius:

- Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at radial-humeral and/or proximal radio-ulnar joint with:
  a. Joint destruction and/or subluxation visible on x-ray; and/or
  b. Resistance to conservative treatment.
- Primary replacement after fracture of the radial head.
- Symptomatic sequelae after radial head resection.
- Revision following failed radial head arthroplasty.

The components are intended for uncemented use.

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.

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510(k) Summary

Avenger Radial Head System

September 2, 2021

Company: In2Bones USA, LLC
6000 Poplar Ave, Suite 115
Memphis, TN 38119
901-260-7931

Primary Contact: Christine Scifert

Company Contact: Rebecca Wahl

Trade Name: Avenger Radial Head System

Common Name: Modular Radial Head

Classification: II

Regulation Number: 21 CFR 888.3170, Elbow joint radial (hemi elbow) polymer prosthesis

Panel: 87-Orthopedic

Product Code(s): KWI

Device Description: The Avenger Radial Head System is a two-piece modular system comprised of cobalt chrome (ASTM F 1537) head and stem components. The system consists of a range of lengths and diameters for the stem as well as heads in a range of diameters and heights to accommodate the patient anatomy. The subject of this 510(k) is to clear a new range of stem implants (+4mm offset stems) that can be used to extend the current range of the Avenger Radial Head® modular system. The implant allows for replacement of the radial head.

Indications for Use

Intended Use:

The Avenger Radial Head System is intended for replacement of the proximal end of the radius:

- Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at radial-humeral and/or proximal radio-ulnar joint with:
  a. Joint destruction and/or subluxation visible on x-ray; and/or
  b. Resistance to conservative treatment.
- Primary replacement after fracture of the radial head.
- Symptomatic sequelae after radial head resection.
- Revision following failed radial head arthroplasty.

The components are intended for uncemented use.

Substantial Equivalence: The subject components were demonstrated to be substantially equivalent to the following systems previously cleared by the FDA:

Primary Predicate

- K192754 – In2Bones Avenger Radial Head System

Additional Predicates

- K991915, K060731 – Wright Medical Evolve® Modular Radial Head

The subject Avenger Radial Head is made of cobalt chrome and has been demonstrated to be substantially equivalent to the previously cleared devices identified above as the products are similar in indications, materials and geometry.

Performance Testing: Head disassembly (ASTM F2009) was performed for the Avenger Radial Head System, +4mm offset stems comparing to the previously cleared K192754 devices. Fatigue testing, sterilization validation and endotoxin testing were able to adopt into the previously cleared devices.

Conclusion

Based on the test results and the comparison to the predicate devices, the subject device is determined to be substantially equivalent to the predicate devices.