Aptis Medical, LLC
% Louise Focht
President
ENMED lntemtional, Inc
PO Box 249
Del Mar, California 92014

May 3, 2019

Re: K190599
Trade/Device Name: Aptis Medical Distal Radio Ulnar Joint Implant
Regulation Number: 21 CFR 888.3810
Regulation Name: Wrist Joint Ulnar (Hemi-Wrist) Polymer Prosthesis
Regulatory Class: Class II
Product Code: KXE
Dated: March 6, 2019
Received: March 8, 2019

Dear Louise Focht:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 CAPT Raquel Peat, PhD, MPH, USPHS
Director
Office of Health Technology 6
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190599

Device Name
Aptis Medical Distal Radio Ulnar Joint Implant

Indications for Use *(Describe)*
The Aptis Medical Distal Radio Ulnar Joint Implant is intended for replacement of the distal radio ulnar joint following ulnar head resection arthroplasty:

Replacement of the distal ulnar head for rheumatoid, degenerative, or post-traumatic arthritis presenting with the following findings:

- Pain and weakness of the wrist joint not improved by non-operative treatment
- Instability of the ulnar head with radiographic evidence of dislocation or erosive changes of the distal radio ulnar joint
- Failed ulnar head resection; e.g. Darrach resection

- Primary replacement after fracture of the ulnar head or neck.
- Revision following failed ulnar head arthroplasty.

This prosthesis is intended for single use only.

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.

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510(k) Summary

Summary of 510 (k) safety and effectiveness information upon which the substantial equivalence determination is based:

I. Submitter

Date Prepared:	April 30, 2019
Device Submitter:	Aptis Medical, LLC 3602 Glenview Ave. Glenview, KY 40025 Establishment Registration Number: 3004521401
Phone:	(502)-523-6738
Contact Person:	Bryan Babb

II. Device

Proprietary Name:	Aptis Medical Distal Radio Ulnar Joint Implant
Common Name:	DRUJ
Classification Name:	Wrist joint ulnar (hemi-wrist) prosthesis
Regulatory Class:	21 CFR 888.3810, Class II
Product Code:	87 KXE

III. Predicate Device

Predicate Device:	Aptis Medical Distal Radio Ulnar Joint Implant Primary predicate: K142569 Additional predicates: K082839, K040497

IV. Device Description

The Aptis Medical Distal Radio Ulnar Joint Implant system, like the predicate device includes various sizes of implants (10-30 and multiple stems) to accommodate the anatomy of the distal ulna. The implants are made from the same materials as the predicate including; Co-Cr, UHMWPe and CPTi. Surgical instruments are also available to facilitate surgical placement of the implant. The implant allows for the replacement of the distal ulnar head.

V. Indications for Use

The Aptis Medical Distal Radio Ulnar Joint Implant is intended for replacement of the distal radio ulnar joint following ulnar head resection arthroplasty:

- Replacement of the distal ulnar head for rheumatoid, degenerative, or post-traumatic arthritis presenting with the following findings:
  - Pain and weakness of the wrist joint not improved by non-operative treatment
  - Instability of the ulnar head with radiographic evidence of dislocation or

erosive changes of the distal radio ulnar joint
- Failed ulnar head resection; e.g. Darrach resection

- Primary replacement after fracture of the ulnar head or neck.
- Revision following failed ulnar head arthroplasty.

This prosthesis is intended for single use only.

VI. Comparison of technological characteristics with the predicate device

The technological characteristics of the Aptis Medical Distal Radio Ulnar Joint Implant are the same as the Aptis Medical predicate device. The device consists of a plate of various sizes which is fixed to the radius and a stem of various sizes which is fixed to the ulna. The principal of operation of the device is the same as that of the predicate.

VII. Performance Data

Evaluation in the MRI environment of the subject device was performed through computational modeling and simulation of radiofrequency induced heating. No clinical data was submitted to support substantial equivalence.

VIII. Conclusions

The Aptis Medical Distal Radio Ulnar Joint Implant when compared to the predicate has the same indications for use, technological characteristics, and principals of operation as the predicate device. The Aptis Medical Distal Radio Ulnar Joint Implant is as safe and effective as the predicate device. This submission does not raise any new types of questions of safety or effectiveness and thus is substantially equivalent to the predicate device.