December 3, 2019

Exsomed Corporation
Michael Zwolinski
Senior Engineering Designer
135 Columbia, Suite 201
Aliso Viejo, California 92656

Re: K192473
Trade/Device Name: Exsomed Wrist Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: August 9, 2019
Received: September 10, 2019

Dear Michael Zwolinski:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192473

Device Name
Exsomed Wrist Plating System

Indications for Use *(Describe)*
The Exsomed Wrist Plating System is intended for the repair of fractures and fusions of the hand and wrist.

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

Submitter Information

Submitters Name:	Exsomed Corporation
Address:	135 Columbia, Suite 201 Aliso Viejo, California 92656
Telephone Number:	855.397.6633
Fax Number:	949.240.6633
Prepared By:	Michael Zwolinski,
Contact Person:	Michael Zwolinski
Date Prepared:	8/8/19

Device Information

Trade Name:	Wrist Plating System
Common Name:	Fixation Plate
Classification Name:	Plate,Fixation,Bone
Device Classification:	Single/multiple component metallic bone fixation appliances and Accessories. Class II per 21 CFR 888.3030 Panel: Orthopedic,
Product Code:	HRS,HWC
Material Composition:	Titanium Alloy (Ti-6AL-4VELI)
Device Description:	The Exsomed Wrist Plating System is a set of implantable metallic (Titanium Alloy) bone plates, locking and non-locking screws of various lengths. The system consists of a series of straight tubular plates of varying lengths as well as a 4-hole carpal fusion plate. Screws are provided for plate fixation in locking and non-locking versions and in Ø2.5 and Ø3.2mm diameters. All of the Implants are made from Titanium Alloy (Ti-6AL-4VELI) per ASTM F136 and are provided non-sterile.
Predicate Devices:	The primary predicate device is the existing Synthes Modular Hand System cleared under 510(k) K030310. Additional predicates include the BIOMET ALPS Hand Fracture System (K081546) and reference device Exsomed Innate (K171558).
Indications for Use:	The Exsomed Wrist Plating System is intended for the repair of fractures and fusions of the hand and wrist.

Technological Characteristics:	The Exsomed Wrist Plating System has been compared to the previously cleared predicate devices in regards to indications for use, materials, and sizes. The Exsomed Wrist Plating system offers plates in similar lengths, widths, and thicknesses as the predicate devices as well as locking and non-locking screws in similar diameters and lengths as the predicate devices. All the Implants in the wrist plating system are manufactured from the same titanium alloy as the Biomet ALPS Predicate (K081546). The Exsomed Wrist Plating System is different from the predicates because the straight plates have a slightly different overall shape than those of the predicate and because The Exsomed system also includes a contoured carpal fusion plate that has transverse screw holes to secure the plate and perform joint arthrodesis. These comparisons demonstrate substantial equivalence to the predicate devices.
Performance Analysis:	Mechanical testing per ASTM F382-17 Annex 1 was performed on the Exsomed Wrist Plating System straight plate and the Synthes predicate device. This showed that the Exsomed Wrist Plating System had a higher bending strength and bending stiffness than the predicate device. Mechanical testing of the Exsomed screws' ultimate torsional strength and insertion and removal torque was performed. The results were compared and demonstrated that the screws did not introduce new issues of safety or effectiveness with respect to insertion and removal torque. Engineering analysis of torsional strength, bending strength and resistance to pullout was conducted on the Exsomed screws and predicate device screws. The results demonstrated that the Exsomed screws do not introduce a new worst case with respect to bending stress, torsional stress and resistance to axial pullout when compared to the predicate devices.
Conclusion:	Based upon comparisons against the predicate devices, Exsomed concludes that the Wrist Plating System is substantially equivalent to the previously cleared predicate devices.