July 15, 2021

Acumed LLC
Janki Bhatt
Regulatory Specialist 3
5885 NE Cornelius Pass Road
Hillsboro, Oregon 97124

Re: K210750
Trade/Device Name: Acumed Clavicle Hook 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: June 14, 2021
Received: June 16, 2021

Dear Janki Bhatt:

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: 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K210750

Device Name

Acumed Clavicle Hook Plating System

Indications for Use *(Describe)*

The Acumed Clavicle Hook Plating System is intended for fixation of lateral clavicle fractures, osteotomies, mal-unions, non-unions and dislocations of the acromioclavicular joint.

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."

510(k) Summary

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Acumed LLC
Applicant Address	5885 NE Cornelius Pass Road Hillsboro OR 97124 United States of America
Applicant Contact Telephone	(503) 718-8753
Applicant Contact	Ms. Janki Bhatt
Applicant Contact Email	janki.bhatt@acumed.net

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Acumed Clavicle Hook Plating System
Common Name	Single/multiple component metallic bone fixation appliances and accessori
Classification Name	Plate, Fixation, Bone and Screw, Fixation, Bone
Regulation Number	888.3030 and 888.3040
Product Code	HRS and HWC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K140259	VariAx Clavicle Hook Plate	HRS
K112111	Acumed Locking Clavicle Plating System	HRS
K140259	VariAx Clavicle Hook Plate (Screws)	HWC

Device Description Summary

21 CFR 807.92(a)(4)

The Acumed Clavicle Hook Plates are intended for fixation of lateral clavicle fractures, osteotomies, mal-unions, non-unions and dislocations of the acromioclavicular joint. This Traditional 510(k) is intended to introduce the Acumed Clavicle Hook Plates to the currently marketed Acumed Locking Clavicle Plating System (K112111). The subject device is being compared to the predicate device, the Stryker Variax Hook Plate (K140259).

The Acumed Clavicle Hook Plating system contains pre-contoured hook plates, 3.5mm locking and non-locking screws and other typical instrumentation for AC joint reduction or distal clavicle fragments cases. All implants are manufactured from Titanium Alloy (Ti 6AL-4V) per ASTM F136 and are provided both sterile and non-sterile.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Acumed Clavicle Hook Plating System is intended for fixation of lateral clavicle fractures, osteotomies, mal-unions, non-unions and dislocations of the acromioclavicular joint.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device, the Acumed Clavicle Hook Plating System, has the same indications for use as the predicate device, the Stryker Variax

Hook Plate. The basis of substantial equivalence for the subject device is the similarities in intended use, material, technology, operating principles, anatomical site for implantation, screw types/diameters and design as the predicate device. Both predicate and subject devices are rigidly fixed to the superior surface of the distal clavicle and include a hook which is positioned below the acromion to provide buttress support to the acromioclavicular joint.

Technological Comparison

21 CFR 807.92(a)(6)

The subject device plates incorporate the same technological characteristics such as design, materials and principles of operation as the predicate device. Both subject and predicate plates are offered in Left and Right specific options for anatomic fit and use locking and non-locking screws to provide rigid fixation, strength, and construct stability. The Acumed Clavicle Hook Plate is made of similar material to the Stryker Variax Clavicle Hook Plate, titanium alloy (Ti-6Al-4V per ASTM F136). The plate lengths, hook depths, widths, and thicknesses of the subject and predicate devices are equivalent. The screw lengths used with the subject and predicate devices are similar as well.

The subject device screws have similar technology and operating principles as the predicate device screws. Both the Acumed Clavicle Hook Plating System Screws and the Stryker Variax Clavicle Hook Plate screws are locking and non-locking screws that provide rigid fixation, strength, and construct stability. The subject device screws are made of the same material as the predicate screws, i.e., titanium alloy (Ti-6Al-4V per ASTM F136). The subject and predicate device screws both consist of headed, fully threaded screws. The screw diameters and lengths available for the subject device screws are similar to those available for the predicate device screws. The subject device locking screws are considered fixed angle, vs the predicate device screws are considered variable angle locking screws, however both screws accomplish the same functional result of a locking plate-screw construct, and hence are considered similar in technology.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The subject plate performance was evaluated by performing static 4-point bending tests in accordance with ASTM F382-17 Annex A1, as well as dynamic 4-point bending tests per ASTM F382-17 Annex A2 to ensure that the design features met the required mechanical strength criteria for their intended use. Within these tests, the performance of the subject device (Acumed Clavicle Hook Plate) was compared to that of the reference device (Acumed Narrow-Profile Clavicle Plate) and based on the results, it was concluded that the subject and reference devices are comparable in performance specifically for the intended use, hence the subject device was proven to be safe and effective for the indication.

The subject screws were evaluated for their torsional strength, insertion torque, and pullout strength per Annex A1, Annex A2, and Annex A3 of ASTM F543-17, and based on the acceptance criteria developed from the FDA Guidance "Orthopedic Non-Spinal Metallic Bone Screws and Washers - Performance Criteria for Safety and Performance Based Pathway" issued December 11, 2020. Based on the results, the subject screws were found to be adequate in performance specifically for the intended use and were considered safe and effective for the indication.

Clinical testing was not required to support substantial equivalence. (Not Applicable)

Based on the results of the nonclinical bench testing described above, it was concluded that the subject, predicate and reference devices are equivalent in performance specifically for the intended use, hence the subject device was proven to be safe and effective for the indication.