September 19, 2023

A2 Medical Systems, LLC
Robert Hall
Chief Operating Officer
6387 Technology Ave.
Kalamazoo, Michigan 49009

Re: K230966
Trade/Device Name: angiOCCLUDE Ligating Clips
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: FZP, DSS
Dated: August 15, 2023
Received: August 16, 2023

Dear Robert Hall:

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,

Tek N. Lamichhane -S

Digitally signed by Tek N. Lamichhane -S
Date: 2023.09.19 11:09:21 -04'00'

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K230966

Device Name
angiOCCLUDE Ligating Clip

Indications for Use *(Describe)*
angiOCCLUDE ligating clips are intended for use in procedures involving ligation of vessels or tissue structures. Surgeons should apply the appropriate size clip for the size of vessel or tissue structure to be ligated based upon their experience, judgment, and needs.

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.

510(k) Summary

510(k) Number: K230966

Name, Address, Phone and Fax Number of Applicant
Owner: Andy Ambro
Phone #: 336-706-6027
Address: A2 Medical Systems, LLC
6387 Technology Ave.
Suite F
Kalamazoo, MI 49009

Contact Person
Robert Hall
Chief Operating Officer
Address: A2 Medical Systems, LLC
6387 Technology Ave.
Suite F
Kalamazoo, MI 49009

Date Prepared: September 18, 2023

A. **Device Name**

Trade Name:	angiOCCLUDE Ligating Clip
Common Name:	Hemostatic Clip, Ligating Clip
Classification Name:	Clip, Implantable

B.

Device Classification:	Class II
Classification Panel:	Cardiovascular & General Surgery
Product Codes:	FZP per 878.4300 DSS per 870.3250

C. **Predicate Devices**

Teleflex Medical Horizon Ligating Clips (510ks; K901303, K982313), Product Codes: DSS (870.3250) and FZP (878.4300)

D. **Clip Device Description**

AngiOCCLUDE ligating clips are permanent implant, non-absorbable, sterile, surgical clips made from an implantable grade of Titanium and are available in six different sizes (micro, small-narrow, small-wide, medium, medium-large and large).

E. **Clip Indications for Use**

angiOCCLUDE ligating clips are intended for use in procedures involving ligation of vessels or tissue structures. Surgeons should apply the appropriate size clip for the size of vessel or tissue structure to be ligated based upon their experience, judgment, and needs.

F. **Contraindications:** angiOCCLUDE ligating clips are never intended for use as a contraceptive tubal occlusion device. This product is also contraindicated when ligating the renal artery during minimally invasive donor nephrectomies**.**

G. **Characteristic Comparison to Predicate Device Equivalence**

The A2 Medical Systems titanium ligating clips are substantially equivalent to the predicate device Horizon in design and use.

a. Substantially Equivalent areas are:
   i. Both will close over vessels
   ii. Both have the same clip material; implantable grade of titanium
   iii. Both have the same clinical application for indications and contraindications
   iv. Both have the same mechanism of action – cartridge and clip design allows for an applier to easily load a clip and clips are then removed for use. When the clip is closing the symmetrical legs pivots in from a centered apex as clips are closed.
   v. Of the five sizes provided MC, SML, M, M/L, and LG; they have the same geometry.
   vi. Both have cartridges that are color coded to match applier ring colors
   vii. Both use traditional EO sterilization processing
   viii. Both use peel open blister packs with either 6 or 24 clips each.
   ix. Both use 4-slides to form the clips

b. Differences:
   i. A2 Medical Systems titanium clips are made in the USA and Horizon is made in Mexico.

H. **Summary of Performance Data**

AngiOCCLUDE ligating clips are made of an implantable grade of Titanium with similar dimensions and metallurgical characteristics as the Teleflex Medical Horizon ligating clips.

a. Substantial Equivalence analyses preformed:
   i. A2 Medical Systems angiOCCLUDE clip to predicate clip dimensional comparison was completed at an open and closed state within an applier that resulted in having the same function as Horizon when clips are applied and closed.
   ii. Both material comparisons prove that the formed and sterilized material used for the angiOCCLUDE clip is as safe and the same as the material used in Teleflex Horizon.
   iii. Quantitative – angiOCCLUDE clip closure testing proved that the clips are secure in the applier, and release from applier's jaws equivalent to Horizon.
   iv. Qualitative - dimensional/geometry comparisons using precise overlays prove that angiOCCLUDE and Teleflex Horizon clips are the same size.
   v. Mechanism of action is the same between angiOCCLUDE and Horizon; cartridge and clip design allows for an applier to easily load a clip, and clips are then removed for use. When the clip is closing the symmetrical legs pivots in from a centered apex as clips are closed.

In summary, the A2 Medical Systems titanium Ligation clips are the same in design, material, and function to the predicate device.

I. **Statement of Substantial Equivalence**

The angiOCCLUDE® Ligating Clips are substantially equivalent to their predicate device; the Teleflex Medical Horizon® Ligating Clips (K901303, K982313), based upon similarities in intended use, design, principles of operation and performance specifications.