March 2, 2022

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

Re: K220006
Trade/Device Name: angioLOCK Polymer Ligating Clip
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: FZP, DSS
Dated: December 30, 2021
Received: January 4, 2022

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,

Mark Trumbore
Assistant Director
DHT4A: Division of General 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)*
K220006

Device Name
angioLOCK Polymer Ligating Clip

Indications for Use *(Describe)*
angioLOCK® Non-Absorbable Polymer Ligation 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 the vessel or tissue structure to be ligated such that the clip completely encompasses the vessel or tissue structure.

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.

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SECTION 5 – 510(k) Summary

510(k) Number: _____

Prior Formal Correspondence: None – Original Submission Prepared 12/29/2021

Basis for the Submission: New Device

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
Phone #: 919-538-2325
E-mail: robert@a2medicalsystems.com
Address: A2 Medical Systems, LLC
6387 Technology Ave.
Suite F
Kalamazoo, MI 49009

Date Prepared

December 30TH 2021

A. **Device Name**

Trade Name:	angioLOCK Polymer 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 Hem-o-lok Ligating Clips (510k – K030311)

D. **Clip Device Description**

AngioLOCK ligating clips are permanent implant, non-absorbable, sterile single use, surgical clips made of implantable grade polymer and are available in multiple sizes.

ligating clips are non-absorbable, non-active implantable devices to be used for ligation of vessels and tissue structures. The clips are made of acetal homopolymer and are offered in three sizes; medium/large, large and x-large. Each clip size is compatible with a corresponding clip applier that may be designed for either general or endoscopic procedures. The clips are supplied in quantities of six according to size in color coded cartridges that are prepackaged sterile and single-use.

angioLOCK® open and Laparoscopic Ligation Clip Appliers are for use as delivery devices for angioLOCK® Non-Absorbable Polymer Ligation Clips. Other ligation clips cannot be used with these appliers. angioLOCK® Laparoscopic Polymer Ligation Clip Appliers are designed for use with specific size cannulas.

E. **Indications For Use:** angioLOCK® Non-Absorbable Polymer Ligation 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 the vessel or tissue structure to be ligated such that the clip completely encompasses the vessel or tissue structure.

F. **Contraindications:** angioLOCK® Non-Absorbable Polymer Ligation Clips are not intended for use as a fallopian contraceptive tubal occlusion device.
angioLOCK® Non-Absorbable Polymer Ligation Clips are contraindicated for use in ligating the renal artery during laparoscopic donor nephrectomies.

G. **Characteristic Comparison to Predicate Device Equivalence**
The A2 Medical Systems polymer ligating clips are substantially equivalent to the predicate device Hem-o-lok in design and use.
    a. Substantially Equivalent areas are:
        i. Both are single use devices
        ii. Both will latch close over vessels
        iii. Both use the same clip Tenac 5010 material: nonabsorbable polyacetal polymer
        iv. Both have the same clinical application for indications and contraindications
        v. Both have the same mechanism of action – cartridge and clip design allow for an applier to easily load a clip, haptic feedback occurs when the clip bosses locate in the applier grooves, and clips are then removed for use. When the clip is closing the upper and lower curved legs with inner teeth pivots in from a hinged section and haptic feedback occurs as clips are latched closed.
        vi. Of the four sizes provided M, M/L, LG, and XLG; they have the same geometry and beam leg height and leg thickness and round boss diameters
        vii. Both have cartridges that are color coded to match applier ring colors
        viii. Both use traditional EO sterilization processing
        ix. Both use peel open blister packs with 6 clips each.
        x. Both use injection molding to form the clips
    b. Differences:
        i. A2 Medical Systems polymer clips are made in the USA and Hem-o-lok is made in Mexico.

H. **Summary of Performance Data**
AngioLOCK ligating clips are made of an implantable grade of polyacetal polymer with same dimensions and same material characteristics as the predicate Teleflex Medical Hem-o-lok ligating clips.
    a. Substantial Equivalence analyses preformed:
        i. A2 Medical Systems angioLOCK 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 Hem-o-lok when clips are applied and closed.
        ii. Both biocompatibility and polymer material comparisons prove that the molded and sterilized material used for the angioLOCK clip is as safe and the same as the material used in Hem-o-lok.
        iii. Qualitative - angioLOCK clip closure testing proved that the clips latch/lock, are secure in the applier, and release from applier's jaws equivalent to Hem-o-lok.
        iv. Qualitative - dimensional/geometry comparisons using precise overlays prove that angioLOCK and Hem-o-lok clips are the same size.
        v. Mechanism of action is the same between angioLOCK and Hem-o-lok; cartridge and clip design allows for an applier to easily load a clip, haptic feedback occurs when the clip bosses locate in the applier grooves, and clips are then removed for use. When the clip is closing the upper and lower curved legs with inner teeth pivots in from a hinged section and haptic feedback occurs as clips are latched closed.

I. **Statement of Substantial Equivalence**
The angioLOCK® Ligating Clips are substantially equivalent to their predicate device; the Teleflex Medical Hem-o-lok® Ligating Clips, based upon similarities in intended use, design, principles of operation and performance specifications.