August 30, 2018

Applied Medical Resources Corp.
Corinne Yestrepsky
Regulatory Affairs Specialist II
22872 Avenida Empresa
Rancho Santa Margarita, California 92688

Re: K182024
Trade/Device Name: Dissecting Balloon System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: July 27, 2018
Received: July 30, 2018

Dear Corinne Yestrepsky:

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,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*

K182024

Device Name
Dissecting Balloon System

Indications for Use *(Describe)*

The Dissecting Balloon System is indicated for patients undergoing laparoscopic surgery requiring tissue separation of the extraperitoneal space.

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) Submitter:	Applied Medical Resources Corp. 22872 Avenida Empresa Rancho Santa Margarita, CA, 92688 (949) 713-8000
Contact Person:	Corinne Yestrepsky, PhD Regulatory Affairs Specialist II Applied Medical Resources Corp. corinne.yestrepsky@appliedmedical.com Tel: (949) 713-8176 Fax: (949) 713-8205
Date of Preparation:	July 27, 2018
Trade Name:	Dissecting Balloon System
Common Name:	Blunt Dissection Balloon
Classification:	Regulation: 21 CFR 876.1500, Endoscope & Accessories Device Class: Class II Product Code: GCJ
Predicate Device:	Preperitoneal Distention Balloon System 510(k)#: K935426 Product Code: GCJ
Device Description:	Applied Medical's Dissecting Balloon System consists of a rigid cannula with an inflatable balloon attached at the distal end that achieves separation of tissue planes during laparoscopic surgery. The system is provided sterile. The system includes three main components: • An introducer that facilitates insertion of the balloon through an abdominal incision. • A dissecting cannula with attached balloon, which is compatible with a 10mm endoscope to allow for visualization during tissue separation. Two balloon configurations will be offered (oval and round). • An inflation bulb that is used to manually inflate the balloon

Indications for use: The Dissecting Balloon System is indicated for patients undergoing laparoscopic surgery requiring tissue separation of the extraperitoneal space.

Comparison of Technological Characteristics with the Predicate Device

The subject and predicate device systems are both blunt dissection balloons intended to separate tissue planes in the extraperitoneal space. Both systems contain an introducer, dissecting cannula with attached balloon, and inflation bulb. The subject and predicate systems are both offered in two balloon configurations (oval and round). Furthermore, each system is compatible with a 10mm endoscope to facilitate visualization of tissue separation.

The subject device system differs from the predicate in that the subject round balloon is encased in a perforated sheath to facilitate insertion where the predicate round balloon is not. Both the predicate and subject oval balloons are encased in a sheath.

Discussion of Performance Testing

The following performance data is provided in support of the substantial equivalence determination.

Biocompatibility

The biocompatibility evaluation for Applied Medical's Dissecting Balloon System was conducted in accordance with the FDA's guidance document, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."* The subject device contacts tissue for a duration of less than 24 hours, so the following endpoints were considered and all materials were found to be biocompatible.

- Cytotoxicity
- Intracutaneous Irritation
- Sensitization
- Acute Systemic Toxicity

Functional Performance

Side-by-side bench top testing was performed with the subject and predicate device systems to demonstrate substantial equivalence. The bench top tests were designed to focus on the functional performance of a blunt dissection balloon device. Both subject and predicate device systems were evaluated for:

- Device insertion
- Tissue separation
- Surgical site visualization
- Balloon deflation and device removal

Conclusion

Results of testing demonstrate that the subject Dissecting Balloon System is substantially equivalent to the predicate Preperitoneal Distention Balloon System, and that the subject device performs comparably to the current marketed device for the same intended use.