May 21, 2020

AnX Robotica Corp.
% Randy Jiang
Senior Consultant
Emergo Global Consulting, LLC
2500 Bee Cave Rd, Bldg 1, Suite 300
Austin, TX 78746

Re: K201106
Trade/Device Name: IntraMarX 3D Radiopaque Marker
Regulation Number: 21 CFR 876.1725
Regulation Name: Gastrointestinal motility monitoring system
Regulatory Class: II
Product Code: FFX
Dated: April 23, 2020
Received: April 24, 2020

Dear Randy Jiang:

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,

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K201106

Device Name
IntraMarX 3D Radiopaque Markers

Indications for Use *(Describe)*
IntraMarX 3D Radiopaque Markers is a diagnostic test indicated for assisting in the evaluation of colonic motility in patients with severe constipation, as diagnosed by a healthcare professional, but otherwise negative GI evaluations. For use in adult, IntraMarX 3D Radiopaque Markers is dispensed only by physicians to patients for oral intake.

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.

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510(k) Summary

IntraMarX 3D Radiopaque Marker

1. Submission Sponsor

AnX Robotica Corp.
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Contact Person: Steven Gu, Director of Quality Assurance and Regulatory Affairs
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2. Submission Correspondent

Emergo Global Consulting, LLC
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Austin, TX 78746
Office Phone: (512) 327-9997
Contact: Randy Jiang
Title: Senior Consultant, Quality and Regulatory

3. Date Prepared

05/4/2020

4. Device Identification

Trade/Proprietary Name:	IntraMarX 3D Radiopaque Marker
Common/Usual Name:	Gastrointestinal Motility Monitoring System
Classification Name:	Gastrointestinal Motility Monitoring System
Regulation Number:	876.1725
Product Code:	FFX
Classification:	II
Classification Panel:	Gastroenterology/Urology

5. Legally Marketed Predicate Device(s):

Device name: IntraMarX Radiopaque Marker
510(k) number: K191087
Manufacturer: Ankon Medical Technologies (Shanghai) Co., Ltd.

6. Indication for Use Statement

IntraMarX 3D Radiopaque Markers is a diagnostic test indicated for assisting in the evaluation of colonic motility in patients with severe constipation, as diagnosed by a healthcare professional, but otherwise negative GI evaluations. For use in adult, IntraMarX 3D Radiopaque Markers is dispensed only by physicians to patients for oral intake.

7. Device Description

The IntraMarX 3D Radiopaque Markers can be used for the diagnosis of many GI conditions, including chronic constipation, colonic inertia, hypomotility and outlet delay. Each of the IntraMarX 3D capsules contains 24 tiny radiopaque rings within the capsule shell. The capsule is swallowed by the patient under the direction of physician. As this capsule moves through the digestive system, the capsule shell will dissolve and leave the rings in the GI tract of the patient; which will show up later during an x-ray scan. Five days after swallowing the capsule, a single x-ray scan of the abdomen will be taken to see the location of the rings and how many are left in the GI tract of the patient. The physician will make evaluations based on the rings remaining and make a diagnosis of GI conditions of the patient.

8. Substantial Equivalence Discussion

The following table compares the IntraMarX 3D to the predicate device with respect to indications for use, principles of operation, technological characteristics, capsule material, and performance, and forms the basis for the determination of substantial equivalence. The subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

Table 5A – Comparison of Characteristics

Attribute	PREDICATE DEVICE		SUBJECT DEVICE		Comparison
Manufacturer	Ankon Medical Technologies (Shanghai) Co., Ltd.		Ankon Medical Technologies (Shanghai) Co., Ltd.		N/A
510(k) Number	K191087		N/A		N/A
Product Code	FFX		FFX		SAME
Regulation Number	876.1725		876.1725		SAME
Indications for Use	IntraMarX Radiopaque Markers is a diagnostic test indicated for assisting in the evaluation of colonic motility in patients with severe constipation, as diagnosed by a healthcare professional, but otherwise negative GI evaluations. For use in adult only, IntraMarX Radiopaque Markers is dispensed by physicians to patients for oral intake.		IntraMarX 3D Radiopaque Markers is a diagnostic test indicated for assisting in the evaluation of colonic motility in patients with severe constipation, as diagnosed by a healthcare professional, but otherwise negative GI evaluations. For use in adult, IntraMarX 3D Radiopaque Markers is dispensed only by physicians to patients for oral intake.		SAME
Models	Ring Double-D Tri-chamber		Ring Dot Tri-chamber		SIMILAR
Mechanism of Action	Intake Orally		Intake Orally		SAME
Capsule Material	HPMC		HPMC		SAME
Radiopaque Marker Material	Polyvinyl Chloride	~45-46%	Thermoplastic Elastomer	50%	SIMILAR
	Tricotyl Trimellitate	~25-25%	None	N/A	DIFFERENT

Attribute	PREDICATE DEVICE		SUBJECT DEVICE		Comparison
	Barium Sulfate	~29-30%	Barium sulfate	50%	SIMILAR
Sterile	No		No		SAME
Single-Use	Yes		Yes		SAME
Shelf Life	2 Years		2 Years		SAME
Capsule number of Inner package box	10 capsules/box		10 capsules/box 3 capsules/box 1 capsule/box		DIFFERENT
Image Area diameter	4.5mm		2.0mm, 3mm, 4.5mm		DIFFERENT
Biocompatibility	Pass		Pass		SAME

9. Non-Clinical Performance Data

To demonstrate safety and effectiveness of IntraMarX 3D and to show substantial equivalence to the predicate device, Ankon completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met. The IntraMarX 3D passed the testing in accordance with internal requirements, national standards, and international standards shown below, supporting its safety and effectiveness, and its substantial equivalence to the predicate device:

- Cytotoxicity testing per ISO 10993-5 – Pass
- Implantation testing per ISO 10993-6 – Pass
- Intracutaneous reactivity testing/Sensitization testing per ISO 10993-10 – Pass
- Material-mediated pyrogenicity /Systemic toxicity testing/Subacute toxicity testing per ISO 10993-11 – Pass
- Radiopacity testing per ASTM F640-12 – Pass

10. Statement of Substantial Equivalence

The IntraMarX 3D has the same intended use as the predicate device, and the same or similar technological characteristics. The differences in technological characteristics do not raise new or different questions of safety and effectiveness. Performance testing has demonstrated the IntraMarX 3D is as safe and effective as the predicate device. Therefore, the IntraMarX 3D is substantially equivalent to the predicate device.