



December 18, 2019

AnX Robotica Corp.
% Giselle Zhang
Consultant, Quality and Regulatory
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, TX 78746

Re: K191087
Trade/Device Name: IntraMarX Radiopaque Markers
Regulation Number: 21 CFR 876.1725
Regulation Name: Gastrointestinal motility monitoring system
Regulatory Class: II
Product Code: FFX
Dated: November 12, 2019
Received: November 19, 2019

Dear Giselle Zhang:

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

Shani P. Haugen, Ph.D.

Acting 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

Indications for Use

510(k) Number (if known)

K191087

Device Name

IntraMarX Radiopaque Markers

Indications for Use (Describe)

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.

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.

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510(k) Summary

IntraMarX Radiopaque Markers

1. Submission Sponsor

AnX Robotica Corp.
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Plano, TX 75024
Contact: Lin Wang
Title: Regulatory Assurance Manager

2. Submission Correspondent

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Office Phone: (512) 327-9997
Contact: Giselle Zhang
Title: Consultant, Quality and Regulatory

3. Date Prepared

12/10/2019

4. Device Identification

Trade/Proprietary Name:	IntraMarX Radiopaque Markers
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): SITZMARKS Capsule

The SITZMARKS Capsule is manufactured by Konsyl Pharmaceuticals, Inc. cleared by K181750 on 11/15/2018. SITZMARKS' Radiopaque Markers are for assisting in the diagnosis of many GI conditions, including chronic constipation, colonic inertia, hypomotility, and outlet delay and bowel obstruction. Each capsule contains 24 radiopaque markers that are visible throughout the digestive tract via X-ray. The markers are available in three different shapes: O-Ring, Double D, and Tri-Chambers.

6. Indication for Use Statement

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.

7. Device Description

The IntraMarX capsule can be used for the diagnosis of many GI conditions, including chronic constipation, colonic inertia, hypomotility and outlet delay. Each of the IntraMarX 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 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 to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, 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	INTRAMARX		SITZMARKS		Comparison
Manufacturer	Ankon Medical Technologies (Shanghai) Co., Ltd.		Konsyl Pharmaceuticals, Inc.		N/A
510(k) Number	K191087		K181750		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.		SITZMARKS capsule is a diagnostic test indicated for aiding in the evaluation of colonic motility in patients with severe constipation, as diagnosed by your healthcare professional, but otherwise negative GI evaluations. SITZMARKS capsule, for use in adult and pediatric patients (at least 2 years old), is to be dispensed only by physicians to patients for oral intake.		SAME
Models	Ring Double-D Tri-chamber		Ring Double-D Tri-chamber		SAME
Mechanism of Action	Intake Orally		Intake Orally		SAME
Capsule Material	HPMC		N/A		NOT KNOWN
Radiopaque Marker Material	Polyvinyl Chloride	~45-46%	Polyvinyl Chloride	~47-48%	SAME
	Tricotyl Trimellitate	~24-25%	Di(2-ethylhexyl) phthalate	~18-19%	DIFFERENT

Attribute	INTRAMARX		SITZMARKS		Comparison
	Barium Sulfate	~29-30%	Barium Sulfate	~33-34%	SAME
Sterile	No		No		SAME
Single-Use	Yes		Yes		SAME
Shelf Life	2 Years		N/A		NOT KNOWN
Cytotoxicity	Pass		Pass		SAME

9. Non-Clinical Performance Data

To demonstrate safety and effectiveness of IntraMarX 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 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
- Sensitization testing per ISO 10993-10 – Pass
- Systemic Toxicity testing per ISO 10993-11 – Pass
- Sample Preparation and Reference Materials testing per ISO 10993-12 – Pass
- Microbial Limit/ Microbial Burden testing per USP 42-NF37:2019 <61> – Acceptable
- Microbial Limit/ Microbial Burden testing per USP 42-NF37:2019 <62> – Acceptable
- Accelerated Aging testing per ASTM F1980-16 – Pass
- Packaging and Transportation testing per ASTM D4332-14 – Pass
- Packaging and Transportation testing per ASTM D4169-16 – Pass
- Extraction of Medical Plastics per ASTM F619-14 – Pass
- Radiopacity testing per ASTM F640-12 – Pass
- Heavy metal testing per ISO 8536-4 – Pass
- Heavy metal testing per ISO 3826-1 – Pass
- Validation Of Analytical Procedures per ICH Q2 (R1) – Pass
- Barium ion precipitation per customer provided protocol – Pass

10. Statement of Substantial Equivalence

The IntraMarX 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 is as safe and effective as the predicate device. Therefore, the IntraMarX is substantially equivalent to the SITZMARKS.