January 18, 2023

Medifactia AB
% Cherita James
Regulatory Consultant
M Squared Associates Inc.
127 West 30th Street
9th Floor
New York, NY 10001

Re: K222000
Trade/Device Name: Transit-Pellets
Regulation Number: 21 CFR 876.1725
Regulation Name: Gastrointestinal motility monitoring system
Regulatory Class: Class II
Product Code: FFX
Dated: December 16, 2022
Received: December 16, 2022

Dear Cherita James:

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,

Sivakami Venkatachalam -S

for
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222000

Device Name

Transit-Pellets

Indications for Use *(Describe)*

For evaluation of colonic transit in adult and pediatric patients (at least 2 years old) with chronic constipation and used to aid in differentiating slow and normal transit constipation.

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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In accordance with 21 CFR 807.92, the following information constitutes the Medifactia AB summary for the Transit-Pellets.

I. Submission Date

January 11, 2023

II. Submitter

Medifactia AB

C/O IOffice Business Center

Kungsgatan 60

Stockholm

Sweden 11122

Contact person: Diana Nyström

Phone number: +46 (0) 31-787 70 77

E-mail: diana.nystrom@medifactia.com

Official Correspondent:

Cherita James

Regulatory Consultant

M Squared Associates, Inc.

127 West 30th St, Floor 9

New York, New York 10001

Ph: 347-954-0624

E-mail: Cjames@Msquaredassociates.com

III. Device

Name of device: Transit-Pellets

Common or usual name: System, Gastrointestinal Motility

Regulatory class: Class II according to 876.1725

Classification code: FFX

Panel: Gastroenterology/Urology

IV. Predicate device

510(k)	Company	Device
Primary: K181760	Medifactia	Transit-Pellets
Reference: K181750	Konsyl Pharmaceuticals	Sitzmarks

V. Device Description

The device is intended to be used for evaluation of colonic transit time in patients with chronic constipation and used to aid in differentiating slow and normal transit constipation in adults and pediatric patients (at least 2 years old). Ten (10) radiopaque markers per day are swallowed for six consecutive days. On day seven an abdominal radiograph is taken. Based on the number of retained markers and the position in colon a colonic transit time is calculated and compared to reference values. Both total transit and segmental transit dysfunction in the colon can be evaluated with the device. By dividing the particle dose on day six by taking five (5) markers in the morning and five (5) markers in the evening, the whole range of transit times (slow, normal, rapid) transit can be measured from the radiograph.

The device is a convenience package of radiopaque markers (22% Barium Sulphate, 78% Elastosil® R 401/60 Silicone rubber) placed in vegetarian capsules from cellulose (HPMC, Hydroxypropyl-methylcellulose), intended for single patient use. The dimension of the markers is 2x4.5mm (ring-formed markers) and 6x2mm (tube-formed markers). The capsules are packed in a blister pack and the blister pack is placed inside a folding box.

There is no change to the Transit-Pellets previously cleared in K181760 for this expanded patient population.

VI. Intended use

For evaluation of colonic transit in adult and pediatric patients (at least 2 years old) with chronic constipation and used to aid in differentiating slow and normal transit constipation.

VII. Comparison of the technology characteristics with the predicate devices

	Subject device	Primary Predicate	Reference Predicate	SE
	Medifactia AB Transit-Pellets	Medifactia AB Transit-Pellets	Konsyl Pharmaceuticals Sitzmarks	
K#	K222000	K181760	K181750	
Indication for use/ Intended use	For evaluation of colonic transit in adult and pediatric patients (at least 2 years old) with chronic constipation and used to aid in differentiating slow and normal transit constipation.	For evaluation of colonic transit in adult patients with chronic constipation and used to aid in differentiating slow and normal constipation.	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.	X
Application	Measuring and using colonic transit time to evaluate patients with chronic (severe) constipation.	Measuring and using colonic transit time to evaluate patients with chronic (severe) constipation.	Measuring and using colonic transit time to evaluate patients with chronic (severe) constipation.	X
Target population	Adult and pediatric patients (at least 2 years old) patients with chronic (severe) constipation.	Adult patients with chronic (severe) constipation.	Adult and pediatric patients (at least 2 years old) patients with chronic (severe) constipation.	X

	Subject device	Primary Predicate	Reference Predicate	SE
	Medifactia AB Transit-Pellets	Medifactia AB Transit-Pellets	Konsyl Pharmaceuticals Sitzmarks	
Anatomical site	Gastrointestinal tract/colon	Gastrointestinal tract/colon	Gastrointestinal tract/colon	X
Where used	Hospitals, clinics	Hospitals, clinics	Hospitals, clinics	X
Design	Ring-formed and tube-formed markers.	Ring-formed and tube-formed markers.	Three different shapes of markers: O Rings, Double D and Tri-Chamber.	X
Dimensions/ Capsule size	2 x 4.5mm, 6 x 2mm Size -00-	2 x 4.5mm, 6 x 2mm Size -00-	1mm x 4.5mm Size -00-	X
Materials	Markers: Barium sulphate, Elastosil® R 401/60 Silicone rubber Capsules: HPMC, Hydroxypropyl-methylcellulose	Markers: Barium sulphate, Elastosil® R 401/60 Silicone rubber Capsules: HPMC, Hydroxypropyl-methylcellulose	Radiopaque Marker • Polyvinyl Chloride Resin (PVC) • Bis(2-ethylhexyl) Phthalate (DEHP) • Epoxides Soya Oil • Calcium/Zinc Stabilizers • Phosphate Stabilizer • Fatty Ester & Polyamide Lubricants • Ultramarine Tinting Agents • Barium Sulfate • Dioctyl Phthalate (DOP) Plasticizer	X

	Subject device	Primary Predicate	Reference Predicate	SE
	Medifactia AB Transit-Pellets	Medifactia AB Transit-Pellets	Konsyl Pharmaceuticals Sitzmarks	
			• Mono & Diglycerides Capsules: Hypromellosa	
Principle of operation	Patient swallows a fixed dose radiopaque marker for a number of days. On day 7 a single abdominal radiograph or fluoroscopy is taken. Based on the number of retained markers on abdominal film and their position in colon a colonic transit time is calculated and compared to reference value.	Patient swallows a fixed dose radiopaque marker for a number of days. On day 7 a single abdominal radiograph or fluoroscopy is taken. Based on the number of retained markers on abdominal film and their position in colon a colonic transit time is calculated and compared to reference value.	Patient swallows a fixed dose radiopaque marker for a number of days. Several abdominal radiographs may be necessary. Based on the number of retained markers on abdominal film(s) and their position in colon a colonic transit time is calculated and compared to reference value.	X
Performance	Colonic Transit Time (CTT/OATT) numerical values reported in *days*.	Colonic Transit Time (CTT/OATT) numerical values reported in *days*.	Colonic Transit Time (CTT/OATT) numerical values reported in *hours*.	X
Biocompatibility	Yes, safe for intended use ISO 10993-5, -10, and -11	Yes, safe for intended use ISO 10993-5, -10, and -11	No information	X
Packaging	Blister and folding box	Blister and folding box	Folder combo/single pack	X
Sterile	No	No	No	X

	Subject device	Primary Predicate	Reference Predicate	SE
	Medifactia AB Transit-Pellets	Medifactia AB Transit-Pellets	Konsyl Pharmaceuticals Sitzmarks	
Shelf life	2.5 years	2.5 years	Unknown	
Rx Only	Yes	Yes	Yes	X

VIII. Performance testing

Transit-Pellets have a size <8mm and are made tube-formed and ring-formed. To test transit characteristics of various types of markers, five types of distinguishable markers in the specific gravity range 1.2-1.6 were examined. The size of the particles was chosen in the range 2-7 mm so that emptying from stomach was likely to occur also with a meal. Transit-Pellets were designed for their size and configurations and are safe and effective for their intended use when compared to the predicate device. Simulated capsule digestion testing in a simulated gastric fluid, dimensional analysis, and mass analysis, as well as the clinical literature provided in the predicate 510k submission (K181760), confirms the device performs as intended for the proposed indication for use, i.e., is safe and effective for evaluation of colonic transit in patients with chronic constipation and used to aid in differentiating slow and normal constipation. The Transit-Pellets is substantially equivalent to Sitzmarks regarding material, technological characteristics, and indications for use.

Biocompatibility testing to ISO 10993-5 and -10 of the Transit-Pellets confirm the device is non-cytotoxic, non- irritant, and non-sensitizing. Testing to ISO 10993-11 confirmed that the Transit-Pellet extracts did not induce a significantly greater biologic reaction than the control following systemic injection and produced a non-pyrogenic response. Additionally, 14 Day Repeat IV and Intraperitoneal Toxicity in Rats did not demonstrate systemic signs of toxicity over 14 days.

Radiopacity Testing in accordance with ASTM F640-12 confirms visibility of the Transit-Pellets for the duration and environment of their intended use during colonic transit.

Medifactia conducted Bite Force testing with both the Transit-Pellets and the reference predicate device to confirm the safe use of the subject device consumed without a capsule in the proposed pediatric population in the event of accidental biting of the markers. The testing concluded that the Transit-Pellets can withstand similar forces as the reference device, when subjected to simulated bite force testing.

IX. Clinical Evidence

A Post-Market Clinical Follow-Up (PMCF) study provided supports the safe and effective use of barium sulphate impregnated particles to measure colonic transit time in pediatric patients at least 2 years old. The literature review carried out during the PMCF study identified 18 clinical investigations performed on similar devices to be of satisfactory quality. In summary, the device performance and safety were successfully measured colonic transit time on 1054 children and young adults. In 12 of the 18 clinical

investigations, the principle of taking markers for six days were applied. No device related adverse event reported in any of the clinical investigations.

Further, a user survey, also part of the PMCF study, confirmed that the Transit-Pellets and the Transit-Pellets principle are used to measure colonic transit time in children and young adults with no adverse events or side-effects identified. The survey also confirmed that some professional users inform patients that they can open the capsules and only swallow the markers. The Transit-Pellets meets the needs of the professional users.

X. Conclusion

The subject and primary predicate device are identical. The subject device includes a patient population of both adults and pediatric patients (at least 2 years old) patients with chronic (severe) constipation which is the same as the reference predicate. All devices share the indication for use of measuring and using colonic transit time to evaluate patients with chronic constipation. The original Transit-Pellets submission (K181760) established substantial equivalence to the reference device for use in adults.

The information provided in this 510(k) support that the Transit-Pellets is substantially equivalent in function, composition, and intended use in a pediatric population to the predicate devices. The proposed device raises no new issues of safety and effectiveness.