August 8, 2019

Medifactia AB
% Connie Qiu
Regulatory Consultant III
M Squared Associates, Inc
575 8th Ave Suite 1212
New York, NY 10018

Re: K181760
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 27, 2018
Received: July 12, 2019

Dear Connie Qiu:

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*
Martha W. Betz, PhD
Acting Assistant Division 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)*
K181760

Device Name
Transit-Pellets

Indications for Use *(Describe)*
For evaluation of colonic transit in adult patients with chronic constipation and used to aid in differentiating slow and normal 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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(K) SUMMARY

510(k) number: K181760

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

## I. Submission Date

July 11, 2019

## II. Submitter

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## III. Device

Name of device: Transit-Pellets
Common or usual name: Radiopaque markers
Classification name: Gastrointestinal motility monitoring system
Regulatory number: 21 CFR 876.1725
Regulation Class: II
Product code: FFX
Panel: Gastroenterology/Urology

## IV. Predicate device

| 510(k) | Company | Device |
|---|---|---|
| K881609 | Lafayette Pharmacal, Inc | Sitzmarks |

## V. Device Description

Transit-Pellets 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. 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.

Transit-Pellets 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.

## VI. Intended use

For evaluation of colonic transit in adult patients with chronic constipation and used to aid in differentiating slow and normal constipation.

## VII. Comparison of the technology characteristics with the predicate devices

| **Device name** | **Company Device** | **Predicate Device** | **SE** |
|---|---|---|---|
| **Applicant** | **Medifactia AB Transit-Pellets** | **Lafayette Pharmacal, Inc Sitzmarks** | |
| **K#** | -- | K881609 | |
| **Indication for use Intended use** | For evaluation of colonic transit in patients with chronic constipation and used to aid in differentiating slow and normal constipation. | For evaluation of colonic transit in patients with chronic constipation and used to aid in differentiating slow and normal constipation. | 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. | X |
| **Target population** | Adult patients with chronic (severe) constipation. | Adult patients with chronic (severe) constipation. | X |
| **Anatomical site** | Gastrointestinal tract/colon | Gastrointestinal tract/colon | X |
| **Where used** | Hospitals, clinics | Hospitals, clinics | X |

| Device name | Company Device | Predicate Device | SE |
|---|---|---|---|
| **Applicant** | **Medifactia AB Transit-Pellets** | **Lafayette Pharmacal, Inc Sitzmarks** | |
| **Design** | Ring-formed and tube-formed markers. | Three different shapes of markers: O Rings, Double D and Tri-Chamber. | X |
| **Dimensions** | 2 x 4.5mm, 6 x 2mm | 1mm x 4.5mm | X |
| **Materials** | Markers: Barium sulphate, Elastosil® R 401/60 Silicone rubber<br><br>Capsules: HPMC, Hydroxypropyl-methylcellulose | Copied from www.sitzmarks.com:<br><br>Markers: Rings-Polyvinylchloride, Barium sulphate, DEHP, soya oil, calcium, zinc, phosphate, ultramarine tinting agent, mono & diglycerides, DOP plasticizer<br><br>Capsules: Hypromellosa<br><br>Copied from 510(k);<br><br>Markers: Radiopaque polyvinyl chloride<br><br>Gelatin capsules | X |
| **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. 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*. ASTM F640-12 RO confirmed. | Colonic Transit Time (CTT/OATT) numerical values reported in *hours*. | X |
| **Biocompatibility** | Yes, safe for intended use<br>ISO 10993-5<br>ISO10993-10<br>ISO 10993-11 | No information | |
| **Packaging** | Blister and folding box | Blister and folding box | X |
| **Sterile** | No | No | X |
| **Shelf Life** | 2.5 years | unknown | X |
| **Rx Only** | 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. In studies with markers of increasing sizes it was observed that markers with a size >8 mm will have a slower emptying rate from the stomach and thus the transit time from the stomach to the colon will be delayed and can lead to a falsely prolonged value of colonic transit time. Studies with markers <8 mm but of different shape showed that the transit through colon was identical with ring-formed, tube-formed and cube-formed markers. For these reasons, the 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 510k submission, 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.

## IX. Clinical Data

Clinical data was not required to establish the substantial equivalence of the subject and predicate devices.

## X. Conclusion

The two devices share the indication for use of measuring and using colonic transit time to evaluate patients with chronic constipation. Applications of our device cover the application of the predicate device and thus the difference will not affect safety and efficiency.

The information provided in this510(k)support that the Transit-Pellets is substantially equivalent in function, composition, and intended use to the predicate devices. The proposed device raises no new issues of safety and effectiveness.