July 22, 2025

Minnesota Medical Technologies
% Gregory Sachs
Consultant
Sachs & Associates, Inc.
16 Crescent Lane
North Oaks, Minnesota 55127

Re: K243367
Trade/Device Name: Minnesota Medical Technologies Fecal Incontinence Insert (My Miracle)
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: Class II
Product Code: PBP
Dated: June 17, 2025
Received: June 17, 2025

Dear Gregory Sachs:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

STEPHANIE COLE -S

for Anthony C. Lee, Ph.D., M.B.A.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243367

Device Name

Minnesota Medical Technologies Fecal Incontinence Insert (My Miracle)

Indications for Use *(Describe)*

The fecal incontinence insert is indicated for the management of accidental bowel leakage (ABL) due to bowel incontinence. The rectal insert is designed for self-insertion to seal and help prevent the involuntary leakage of stool from the rectum.

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
Minnesota Medical Technologies Fecal Incontinence Insert

I. SUBMITTER

Minnesota Medical Technologies
2446 Henry Road NW, Stewartville, MN 55976

Contact person: Robert Anglin, VP, Quality & Regulatory
Phone: 507-533-0366
Fax: 507-533-0388
Date prepared: October 28, 2024

II. DEVICE

Name of the device: Minnesota Medical Technologies Fecal Incontinence Insert
Common name: Rectal Insert
Regulation number: 21 CFR 876.5980
Regulation name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: PBP

III. PREDICATE DEVICE

Renew Medical Inc., Renew Insert, K122003

Reference device: Eclipse System DEN140020

IV. DEVICE DESCRIPTION

The device is a simple rectal insert which is used to control accidental bowel leakage in adult patients. The single use device is inserted via the anus into the anal canal and rectum. The device engages with and conforms to the anorectal junction and the anal canal to control the accidental leakage of fecal matter.

The device consists of two components: a soft, pre-lubricated, liquid- filled silicone Insert device, and a plastic applicator. The Insert device is soft and flexible which allows engagement with the anorectal junction and the anal canal. The applicator is preassembled inside the Insert device to facilitate insertion of the device and is removed and discarded after the device is in place. The device is available in two sizes, Standard and Large. The device is provided preassembled and non-sterile in individual single-use packages.

V. INDICATION FOR USE

The Fecal Incontinence Insert is indicated for the management of Accidental Bowel Leakage (ABL) due to bowel incontinence. The rectal insert is designed for self-insertion to seal and help prevent the involuntary leakage of stool from the rectum.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

At a high level, the subject and predicate device are based on the following same technological elements:

• Product Code • Device Classification Name • 21 CFR Regulation Number • Indications for Use • Principle of Operation • Patient Population • Anatomical Site • Location Where Used • Placement/Human Factors • Single Use Only • Provided Non-sterile • Packaging • Assembly • Applicator	• Diameter • Shaft Length • Strength Test • Detachment Test • Puncture Test • Buckling Test • Bending Test • Packaging Integrity • Instructions For Use • Labeling • Warning, Precautions • Shelf Life • Applicator Material • Biocompatibility Test Results

The following technological differences exist between the subject and predicate device:

• Anorectal Junction Sealing Feature • Shaft Configuration • External Retaining Feature at Anus • Sizes (different in name only) • External Retainer Diameter • Simulated Use Testing Results	• Contraindications • Disk or Bulb Material • Shaft Material • External Retainer Material • Patient Lube

VII. NON-CLINICAL PERFORMANCE DATA

Bench Testing

The following bench performance data was provided in support of the substantial equivalence.

- Strength Test
- Detachment Test
- Puncture Test
- Buckling Test
- Bending Test
- Sealing Function in Simulated Use
- Package Functional Testing
- Package Stability Testing
- Shelf Life Testing

Biocompatibility Testing

The device was assessed in accordance with ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process. The following tests were performed per GLP:

- ISO 10993-5, Cytotoxicity Using the ISO Elution Method
- ISO 10993-10, ISO Guinea Pig Maximization Sensitization Test
- ISO 10993-10, Rectal Irritation Study in Rabbits
- ISO 10993-11, Material Mediated Pyrogenicity
- ISO 10993-3, Bacterial Reverse Mutation Study
- ISO 10993-3, Mouse Lymphoma Assay

A biological risk assessment was performed to identify areas of concern to be addressed by literature review, clinical experience, and testing with consideration given to type of patient contact, potential hazards of the materials of construction, the history of clinical use, and testing of the materials of construction, biocompatibility and chemical characterization testing on the device, and other information available in the literature.

Based upon examination of the device materials and test results, use of the Minnesota Medical Technologies Fecal Incontinence Insert would not be expected to result in an adverse biological response when used as intended.

Based on the design verification performance, the Minnesota Medical Technologies Fecal Incontinence Insert was found to have a safety and effectiveness profile that is substantially equivalent to the predicate device.

VIII. CLINICAL PERFORMANCE DATA

A prospective, open label, single-arm, non-randomized clinical study designed to establish the safety and effectiveness of the Minnesota Medical Technologies Fecal Incontinence Insert in subjects with fecal incontinence. The US clinical trial was performed with male and female patients, aged 18 and above, with a diagnosis of fecal incontinence and have also failed conservative medical therapy and biofeedback therapy as appropriate for fecal incontinence. The trial consisted of a 4-week baseline evaluation period, a 4-week fitting period, and a 4-week treatment period.

Effectiveness of the insert was evaluated by the primary effectiveness endpoint:

> A relative percentage change in episodes of Accidental Bowel Leakage (ABL) determined by comparing treatment results to pre-treatment results from the baseline period as measured by daily diary recordings.

The primary endpoint was satisfied with 44 of 58 subjects (75.9%, 95% CI: 62.8%, 86.1%) achieved a $\geq$ 50% reduction in ABL episodes demonstrating a highly significant device effect ($p < .0001$).

Safety of the insert was evaluated through safety endpoints which included adverse events, serious adverse events, unanticipated serious adverse events, device deficiencies, and device malfunctions.

The safety population included all 124 enrolled subjects (enrolled = signed informed consent prior to initial screening). There were 15 adverse events (AEs) reported in 12 subjects of which ten AEs were not related to the device, where one of these was serious. Three AEs were classified as possibly related to the device, one AE was classified as probably related to the device, and one AE was classified as definitely related to the device. The one AE classified as definitely related to the device was device over-insertion or device migration into the anal canal or rectum.

There were no device-related serious AEs, or unanticipated serious AEs. There were no device deficiencies or malfunctions.

After the treatment period, all individuals who withdrew from the study for reasons other than personal preference (i.e., for medical reasons) and a minimum of 50% of all subjects who completed the study, underwent an evaluation by anoscopy following the treatment period to assess for device related trauma. No patients necessitated an anoscopy due to new anorectal bleeding or moderate or severe pain noted in the bowel diary. Post-

treatment period anoscopy results do not show evidence of insert-related trauma.

Comparison of the insert to the predicate shows that the insert performs as well as or better than the legally marketed predicate device. The clinical trials for the proposed device and predicate device have similar design, compared a treatment period to a baseline period, and were performed on male and female adult patients with a diagnosis of fecal incontinence.

The clinical study results support that the Minnesota Medical Technologies Fecal Incontinence Insert is safe and effective when used for the intended purpose. The clinical performance (safety and effectiveness) of the insert support the determination of substantial equivalence of the insert to the predicate device.

IX. SUBSTANTIAL EQUIVALENCE

The indication for use for the Minnesota Medical Technologies Fecal Incontinence Insert is substantially equivalent to the predicate. The technological characteristics of the Minnesota Medical Technologies Fecal Incontinence Insert are similar to the predicate device. Both the proposed device and the predicate device have a bar-bell design which incorporates both an internal and external retention feature which are connected by a central shaft. Both are inserted with a removable applicator. Both control accidental bowel leakage through engagement of the device with the anorectal junction.

The Minnesota Medical Technologies Fecal Incontinence Insert has the same intended use, patient population, and anatomical sites as well as similar technological characteristics as the predicate device. The differences in technological characteristics have been analyzed and addressed through testing and clinical evaluation. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness.

The nonclinical and clinical testing demonstrate that the Minnesota Medical Technologies Fecal Incontinence Insert is as safe, as effective, and performs as well as or better than the predicate device. Thus, the Minnesota Medical Technologies Fecal Incontinence Insert is substantially equivalent to the predicate device.

X. CONCLUSION

Based on the same indications for use, technological characteristics, performance testing, and clinical evaluation, safety, and performance, the Minnesota Medical Technologies Fecal Incontinence Insert, is substantially equivalent to the Renew Medical, Inc. Renew Insert (K122003).