August 20, 2026

Cm Technologies, Inc.
% Alan Donald
President
Matrix Medical Consulting, Inc.
Hyundai Office Bldg.
8880 Rio San Diego Dr., Suite 800
San Diego, California 92108

Re: DEN250043
Trade/Device Name: Qoramatic Automated Stool Management
Regulation Number: 21 CFR 876.5230
Regulation Name: Powered fecal management system
Regulatory Class: Class II
Product Code: SJB
Dated: September 12, 2025
Received: September 15, 2025

Dear Alan Donald:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Qoramatic Automated Stool Management, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The Qoramatic Automated Stool Management device is intended for fecal management by diverting and collecting liquid or semi-liquid stool to minimize skin contact in bedridden patients. Adults use only.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Qoramatic Automated Stool Management, and substantially equivalent devices of this generic type, into Class II under the generic name powered fecal management system.

FDA identifies this generic type of device as:

> **Powered fecal management system**. A powered fecal management system is a device that uses powered components to partially or fully divert and contain fecal waste away from a bed-ridden patient. This classification includes accessories such as filters, conduits for fecal waste transfer, and receptacles for fecal waste containment.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On September 15, 2025, FDA received your De Novo requesting classification of the Qoramatic Automated Stool Management. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Qoramatic Automated Stool Management into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the Qoramatic Automated Stool Management can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risk to Health	**Mitigation Measures**
Tissue injury, irritation, or inflammation due to: • Extended device placement and duration of use • Device failure or malfunction of fecal waste diversion and containment features • Insufficient fecal waste diversion and containment • Device withdrawal/expulsion • Use error	Clinical performance data Non-clinical performance testing Software verification, validation, and hazard analysis Labeling
Infection due to insufficient fecal waste diversion and containment	Clinical performance data Non-clinical performance testing Software verification, validation, and hazard analysis Labeling
Device malfunction leading to injury to user/patient (e.g., shock, burn, interference)	Non-clinical performance testing Electrical safety testing Software verification, validation, and hazard analysis Electromagnetic compatibility testing Labeling

	Shelf life testing
Adverse tissue reaction	Biocompatibility evaluation

In combination with the general controls of the FD&C Act, the powered fecal management system is subject to the following special controls:

(1) Clinical performance data must demonstrate that the device performs as intended under its anticipated conditions of use in all intended use environments. Data must include:
   (i) Records of powered device operation over the duration of clinical use;
   (ii) Device failures; and
   (iii) All adverse events, including fecal leakage and any adverse events during insertion, operation, and withdrawal of the device.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under its anticipated conditions of use and all intended use environments. The testing must include:
   (i) Simulated testing of fecal waste diversion and containment with powered functions for the expected duration of use; and
   (ii) Evaluation of pressures exerted on and within the rectum during insertion, operation, and withdrawal of the device over the intended duration of use.

(3) The patient-contacting components of the device must be demonstrated to be biocompatible.

(4) Software verification, validation, and hazard analysis must be performed.

(5) Performance data must demonstrate the electromagnetic compatibility, electrical safety, and mechanical safety of the device.

(6) Performance data must support the shelf life of the device by demonstrating continued package integrity and device functionality over the labeled shelf life.

(7) Labeling must include:
   (i) Intended duration of use for the device;
   (ii) Information on each powered function, including how operators can monitor and control any powered function; and
   (iii) A summary of the clinical data pertinent to use of the device, including device-related complications or adverse events.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device

type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the powered fecal management system they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 Management System Regulation (QMSR) (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 FD&C Act; 21 CFR 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.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Virag Patel at (301) 796-0452.

Sincerely,

SHANIL P. HAUGEN -S

Shanil P. Haugen, Ph.D.
Acting 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