November 17, 2021

CM Technologies, Inc.
% Alan Donald
President
Matrix Medical Consulting, Inc.
8880 Rio San Diego Drive, Suite 800
San Diego, CA 92108

Re: K212444
Trade/Device Name: Qora® Stool Management Kit
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: KNT
Dated: October 11, 2021
Received: October 19, 2021

Dear Alan Donald:

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 and Part 809); 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,

Je Hi An, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K212444

Device Name
Qora® Stool Management Kit

Indications for Use *(Describe)*
The Qora® Stool Management Kit is indicated for fecal management by diverting and collecting liquid or semi-formed stool to minimize skin contact with bedridden patients. The device is for use in patients 18 years and older only. The uninterrupted use of this device, including replacement with other same devices, should not exceed 29 days.

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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SECTION 5 Special 510(k) Summary

This summary of safety and effectiveness for the Qora® Stool Management Kit is being submitted in accordance with the requirements of 21 CFR 807.92.

510(k) Number:

Name: CM Technologies, Inc.
Address: 2165 San Diego Avenue, San Diego, CA 92110
Owner Operator Number: 10049590
Establishment Registration: 3013524793
Phone: (858) 243-3582
Contact: Alan Donald

Date Prepared: July 20, 2021

Trade Name: Qora® Stool Management Kit
Common Name: Rectal Catheter
Classification: 21 CFR 876.5980; Gastrointestinal Tube and Accessories
Product Code: KNT
Regulatory Class: Class II

Identification of the legally marketed predicate device

The modifications described herein relate to the Qora AIM™ Stool Management Kit, the legally marketed predicate device, with further details below.

Table 1: Legally Marketed Predicate Device

510(K) Identifier:	K153506	**Regulation Name:**	Gastrointestinal Tube and Accessories
Trade/Device Name:	Qora AIM™ Stool Management Kit	**Regulatory Class:**	Class II
Device Type/Common Name:	Rectal Catheter	**Product Code:**	KNT
Regulation Number:	21 CFR 876.5980	**Clearance Date:**	May 6, 2016

For this submission, the modified device, the Qora® Stool Management Kit, is compared with the Qora AIM™ Stool Management Kit, which was cleared in the company's 510(k) (ref. K153506).

Description of the modified device
Similar to the predicate device, the modified device is a non-sterile, single-use device intended to use for the management of fecal incontinence in bedridden patients. The device consists of an indwelling diverter, an external transit sheath, and an external collection bag. The kit also includes a collection bag hanger and a transit sheath clamp.
The self-conforming indwelling fecal diverter, which is provided pre-loaded into a hygienic applicator used to deploy inside the rectum, remains in place by apposition to the rectal wall when deployed. The transit sheath acts as a conduit to facilitate the transfer of fecal matter from the indwelling diverter to the collection bag. The device includes three ports attached to the transit sheath, to facilitate irrigating of the indwelling diverter and fluid delivery, sample collection, and to allow withdrawal in a trauma-free manner.

Indications for Use
The Qora® Stool Management Kit is indicated for fecal management by diverting and collecting liquid or semi formed stool to minimize skin contact in bedridden patients. The device is for use in patients 18 years and older only. The uninterrupted use for this device, including replacement with other same devices, should not exceed 29 days.
Note: *There has been no modification to the Indications for Use statement other than the product name which has been changed from Qora AIM™ Stool Management Kit to Qora® Stool Management Kit.*

Substantial Equivalence

Table 2: A summary of equivalence between the modified and the predicate device is given below:

Description	Modified Qora® SMK	Predicate Device (K153506)	Result
Intended Use	Fecal management	Fecal management	Identical
Intended Users	Bedridden patients	Bedridden patients	Identical
Indications for Use	The Qora® *Stool Management Kit* is indicated for fecal management by diverting and collecting liquid or semi-formed stool to minimize skin contact with bedridden patients. The device is for use in patients 18 years and older only. The uninterrupted use of this device, including replacement with other same devices, should not exceed 29 days.	The Qora® *AIM Stool Management Kit* is indicated for fecal management by diverting and collecting liquid or semi-formed stool to minimize skin contact in bedridden patients. The device is for use in patients 18 years and older only. The uninterrupted use for this device, including replacement with other same devices, should not exceed 29 days.	Identical
Patient Population	18 years and older	18 years and older	Identical
Environment of Use	Hospitals and Nursing Homes	Hospitals and Nursing Homes	Identical
Condition of Use	Single-use	Single-use	Identical
Period of Usage	29 days	29 days	Identical
Insertion Method	Hygienic Applicator	Hygienic Applicator	Identical
Diverter OD	55mm ± 10mm	55mm ± 10mm	Identical
Detachable Collection Bag	Yes	Yes	Identical
Irrigation Port	Yes	Yes	Identical
Sampling Port	Yes	Yes	Identical
Retrieval By	Collapsing Diameter	Collapsing Diameter	Identical
Interface Port	Side catheter connector port	Side catheter connector port	Identical
Odor Protection	Yes	Yes	Identical
Sterility	Supplied non-sterile, disposable, single patient use	Supplied non-sterile, disposable, single patient use	Identical
Shelf Life	12 months	12 months	Identical
MR Safety	Non-clinical testing demonstrated that the Qora® SMK is MR Conditional. Conditions for MRI Testing were revised based on the updates to the indwelling diverter	Non-clinical testing demonstrated that the Qora AIM™ SMK is MR Conditional.	Reconfirmed /Identical See Note 1

Note 1: *MR testing of the modified device was performed by the same independent laboratory, following the same applicable ASTM standards and US FDA guidance document, (Testing and Labeling Medical Devices for Safety in the MR environment, May 2021), as those for the predicate device. The test results of the modified device were found to be within the same acceptable range for Conditional usage as those cleared for Qora AIM™ SMK under K153506.*

Description of Change

No design change has been made that would alter the technology used in the modified device. However, to improve manufacturability, and due to raw material availability, the stainless-steel wire in the indwelling diverter has been modified. This new wire allows the diameter to be increased by a small amount (0.09mm) without impacting the patient safety or device functionality, as demonstrated from the non-clinical tests performed.

The name of the product has been changed to Qora Stool Management Kit for marketing purposes.
Corresponding label changes have been made to the Instructions For Use to reflect the name change and updated MR conditions. The labeling is in compliance with the US FDA guidance document, Testing and Labeling Medical Devices for Safety in the MR environment, May 2021.

Summary of Non-clinical Testing

Validation and verification testing, primarily dimensional and mechanical force testing, identical to that performed on the original device, were performed on the modified device/components to ensure that the performance of the modified device is equivalent to the performance of the predicate device. The modified device met all previous device specifications for the predicate device.

No additional biocompatibility testing was required by the modification of the diverter wire. Other minor changes did not involve patient contact materials.

Conclusions from Nonclinical Testing

The Qora® Stool Management Kit is fundamentally equivalent in design and function to the predicate device, the Qora AIM™ Stool Management Kit.

Qora® Stool Management Kit incorporates the similarities with the predicate device, the Qora AIM™ Stool Management Kit as shown in the above comparison table. The few differences, including this described modification, do not introduce any new issues of safety or effectiveness.

In summary, Qora® Stool Management Kit described in this submission is substantially equivalent to the predicate Qora AIM™ Stool Management Kit.