DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 6, 2016

Consure Medical Pvt Ltd.
% Alan Donald
President
Matrix Medical Consulting, Inc.
8880 Rio San Diego Drive, Suite 800
San Diego, CA 92108

Re: K153506
Trade/Device Name: Qora AIM™ Stool Management Kit, Qora Aeon™ Stool Management Kit, Qora Arida™ Stool Management Kit
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: Class II
Product Code: KNT
Dated: March 23, 2016
Received: April 4, 2016

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153506

Device Name
Qora AIM Stool Management Kit
Qora Aeon Stool Management Kit
Qora Arida Stool Management Kit

Indications for Use *(Describe)*

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.

The Qora Aeon 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.

The Qora Arida 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 is intended to be until the collection pouch is filled or until it has been utilized for 72 hours, whichever comes first. The 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.

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SECTION 5 510(k) Summary

Device/Trade Name(s):	Qora AIM™ Stool Management Kit Qora Aeon™ Stool Management Kit Qora Arida™ Stool Management Kit
Device Type/Common Name:	Rectal Tube
510(k) Submitter:	Consure Medical Pvt. Ltd 5L, Third Floor Shahpur Jat New Delhi, Delhi 110049 INDIA Contact: Mr.Nishith Chasmawala, CEO Phone: +91 99 1002 8379, +91 11 4161 7344
Establishment Registration Number:	3011802696
Address Of Manufacturing/Packaging Facility:	Contract Medical International GmbH. Lauensteiner Strasse 37 Dresden 01277 Germany Contact: Mr. Jan Kloboucnik, QA/RA Director Telephone: +42 494 949 564
Authorized Contact Person:	Alan Donald, President Matrix Medical Consulting, Inc. 8880 Rio San Diego Drive, Suite 800 San Diego, California 92108 Phone: +1 619 359 4103 Fax: +1 858 753 1801
Recommended Regulation:	21 CFR 876.5980
Device Classification Name:	Gastrointestinal Tube and Accessories
Device Class:	Class II
Panel:	Gastroenterology-Urology Devices
Product Code:	KNT
Predicate Device:	Consure 120 SMS
Predicate Device Product Code:	KNT, 510(k) K133465
Date Summary Prepared	May 4, 2016

Device Descriptions

Fecal incontinence (FI) is the inability to control bowel movements resulting in the involuntary and untimely release of feces or flatus. Although FI is a benign condition, its clinical sequelae are often devastating to both the patient and the health system. The condition is believed to affect 8-15 percent of the general population, with the highest prevalence among the elderly and in acute care settings.

The Qora AIM™, Qora Aeon™, and Qora Arida™ Stool Management Kits are non-sterile, single-use devices packaged in a product box. Each kit contains one hygienic device applicator that houses a soft indwelling fecal diverter. The Qora AIM™ and Qora Aeon™ kits contain an additional two odor-proof collection bags.

The primary component of the device is the fecal diverter. It consists of soft, pliable, and self-expanding indwelling diverter that remains apposed to the rectal wall and the transit sheath. The indwelling diverter is sufficiently compliant to collapse and expand with the adjacent anatomy during peristaltic contractions of the rectum. This pliancy within the rectum is designed to help reduce abrasion and subsequent clinical complications. An applicator is used to hygienically insert and deploy the indwelling diverter at the intended location inside the rectum.

The Qora Arida™ collection pouch is a thin, biocompatible conduit that facilitates the transfer and collection of fecal material from the indwelling diverter. The use of thin material is engineered to reduce the foreign body sensation and risk of anal sphincter dysfunction. Furthermore, the Qora Arida™ kit offers a single port attached to the side of the collection pouch. The port is used to withdraw the device in a trauma-free way from the patient.

The Qora AIM™ and Qora Aeon™ kits utilize a transit sheath that is a thin, biocompatible conduit that facilitates the transfer fecal material from the indwelling diverter to the collection bag. The use of thin sheath is designed to reduce the foreign body sensation and risk of anal sphincter dysfunction. The bag connection interface at the end of the transit sheath prevents accidental soiling of bed sheets, garments, etc. during the exchange of a collection bag or other regular maneuvers during patient handling. Furthermore, the Qora AIM™ and Qora Aeon™ kits offer three ports attached to the side of the transit sheath. One port is used to irrigate the indwelling diverter if needed. The second port is used to collect samples from within the transit sheath if desired. The third and final port is used to withdraw the device in a trauma-free way from the patient.

Indications for Use

The Indications for Use for the three products are as below:

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.

The Qora Aeon™ 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.

The Qora Arida™ 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 is intended to be until the collection pouch is filled or until it has been utilized for 72 hours, whichever comes first. The replacement with other same devices should not exceed 29 days.

Substantial Equivalence

A summary of the equivalence between the Qora AIM™ Stool Management Kit, Qora Aeon™ Stool Management Kit, and Qora Arida™ Stool Management Kit and the predicate device is given in the following table.

Parameter	MODIFIED DEVICES			PREDICATE
	Qora AIM™ SMK	**Qora Aeon™ SMK**	**Qora Arida™ SMK**	**Consure 120 SMS (K133465)**
Intended Use	Fecal management	Fecal management	Fecal management	Fecal management
Intended Users	Bedridden patients	Bedridden patients	Bedridden patients	Bedridden patients
Indications For Use	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.	The Qora Aeon™ 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.	The Qora Arida™ 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 is intended to be until the collection pouch is filled or until it has been utilized for 72 hours, whichever comes first. The replacement with other same devices should not exceed 29 days.	The Consure 120 SMS is indicated for fecal management by diverting and collecting liquid or semi-formed stool to minimize skin contact in bedridden patients.
Patient Population	18 years and older	18 years and older	18 years and older	18 years and older
Environment Of Use	Hospitals and nursing homes	Hospitals and nursing homes	Hospitals and nursing homes	Hospitals and nursing homes
Condition Of Use	Single use	Single use	Single use	Single use
Period Of Usage	29 days	29 days	29 days	5 days
Insertion Method	Hygienic Applicator	Hygienic Applicator	Hygienic Applicator	Hygienic Applicator
Diverter Outer Diameter	55mm	55mm	55mm	55mm
Detachable Collection Bag	Yes	Yes	No	Yes

Irrigation Port	Yes	Yes	No	Yes
Sampling Port	Yes	Yes	No	No
Retrieval By	Collapsing diverter	Collapsing diverter	Collapsing diverter	Collapsing diverter
Closed Waste Bag Volume	Approximately 1 liter	Approximately 1 liter	Approximately 1.5 liter	Approximately 1 liter
Interface Port	Side catheter connector port	Side catheter connector port	Side catheter connector port	Side catheter connector port
Odor Protection	Yes	Yes	No	No
Materials	*Diverter*: Urethane based TPU that cushions stainless steel wire form lattice that is MRI Safe. Urethane base TPU film to divert fecal matter into collection bag. *Collection Bag*: Hypoallergenic EVA/PVDC odor barrier film.	*Diverter*: Urethane based TPU that cushions stainless steel wire form lattice. Urethane base TPU film to divert fecal matter into collection bag. *Collection Bag*: Hypoallergenic EVA/PVDC odor barrier film.	*Diverter*: Urethane based TPU that cushions stainless steel wire form lattice. Urethane base TPU film to divert fecal matter into collection bag. *Collection Bag*: Urethane based TPU film	*Diverter*: Urethane based TPU that cushions stainless steel wire form lattice. Urethane base TPU film to divert fecal matter into collection bag. *Collection Bag*: Urethane based TPU.
Sterility	Supplied non-sterile, disposable, single patient use.	Supplied non-sterile, disposable, single patient use	Supplied non-sterile, disposable, single patient use	Supplied non-sterile, disposable, single patient use.
Packaging	Device tray in tamper proof duplex box.	Device tray in tamper proof duplex box.	Device in tamper proof duplex box.	Cardboard tray in Tyvek Pouch.

Summary of Performance Data (Non-Clinical Testing):
Non-clinical testing of the subject devices for structural and functional use characteristics has been performed (lumen size, device dimensions, functional strength, material strength, simulated use, etc.). In this testing, the subject devices were found to be substantially equivalent to the predicate device for dimensional, functional, and structural integrity testing.

The components of the Qora AIM™, Qora Aeon™, and Qora Arida™ Stool Management Kits have been evaluated for biocompatibility in accordance with the U.S. Food and Drug Administration's guidance entitled *Use of International Standard 180 -10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing', issued May 1, 1995*. The results of this testing demonstrate that the Qora AIM™, Qora Aeon™, and Qora Arida™ Stool Management Kits are considered to be non-sensitizing, non-cytotoxic, and non-irritating, and has been found safe in such respect for its intended use.

This 510(k) submission for the Qora AIM™ Stool Management Kit, Qora Aeon™ Stool Management Kit, and the Qora Arida™ Stool Management Kit is intended to address line extensions to the previously FDA cleared Consure 120 SMS (K133465). Based on the comparison of intended use, indications for use, and technological characteristics, the three line extensions are substantially equivalent to the Consure 120 SMS (K133465), with respect to intended use, indications for use, performance, and technological characteristics. The line extensions do not raise any new issues of safety or effectiveness.