5 510(k) Summary of Safety and Effectiveness

Device / trade name:	Consure 120 SMS™
Device type / Common Name:	Rectal Catheter
510(k) submitter:	Consure Medical, Pvt., Ltd. 86/1 Shahpur Jat Village, Building No.1, 1st Floor, New Delhi, Delhi – 110 049 INDIA Contact: Mr. Nishith Chasmawala, CEO
Establishment registration number:	Not obtained yet. Note: The product is manufactured and packaged by Contract Medical International GmbH, a contract manufacturer.
Address of manufacturing/packaging facility:	Contract Medical International GmbH. Lauensteiner Strasse 37 Dresden 01277 Germany Telephone: +42 494 949 564 Contact: Mr. Jan Kloboucnik
Authorized Contact Person:	Alan Donald, President Matrix Medical Consulting, Inc. 11440 West Bernardo Court, Suite 300 San Diego, California 92127-1644 Phone: 858 485 8584 Fax: 858 753 1801
Recommended regulation:	21 CFR 876.5980
Device classification name:	Gastrointestinal tube and accessories
Device class:	Class II device
Panel:	Gastroenterology-Urology Devices
Product code:	KNT
Predicate device:	Bard® DigniShield™ Stool Management System
Predicate Device Pro Code/K#:	KNT, 510(k) K102391
Date Summary Prepared:	November 6, 2013

Device Description:

Fecal incontinence (FI) is the inability to control bowel movements resulting in involuntary leakage or soiling. The condition is believed to affect 8-15 percent of the general population, with the highest prevalence among the elderly and in acute and ICU care settings.

The Consure 120 Stool Management System is a non-sterile device packaged in individual SteriClin (medical grade paper with peel-away PE lamination) pouches. Ten such individual pouches are packed in corrugated boxes for shipping. Each Consure 120 SMS pouch contains:

-- 1 soft and hygienic applicator that houses a soft in-dwelling diverter and
-- 3 collection bags.

The primary component of the device is the fecal diverter. It consists of an indwelling, pliable, self-expanding lattice structure 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 can reduce abrasion and subsequent clinical complications originating from the mucosal damage. The transit sheath is a thin, biocompatible conduit that facilitates the transfer fecal material from the indwelling diverter to the collection bag. The use of thin sheath reduces the foreign body sensation and risk of anal sphincter dysfunction.

The applicator is used to hygienically insert and deploy the indwelling diverter at the intended location inside the rectum. Whereas the bag connection interface allows the prevention of accidental soiling of bed sheets, garments, etc. during exchange of collection bag or other regular maneuvers during patient handling.

Indications for Use:

Consure 120 SMS is indicated for fecal management by diverting and collecting liquid or semi-formed stool to minimize skin contact in bedridden patients.

Testing

1) In addition to 100% receiving and in-process inspection, the following tests are performed on each lot prior to release. These tests (Table I below) confirm the functional performance and structural integrity of the product.

2) Comparative analysis of Consure 120 SMS vs predicate devices for dimensional and functional parameters. The comparison was performed in-house with the aid of published functional parameters of predicate devices. Refer to Table II.

3) Biocompatibility testing per ISO 10993 for all components that has mucosa contact (for more than 60 seconds). Refer to Table III

Table I: *Functional Performance and Structural Integrity Testing.*

Product Components/Feature	Dimension	Test Method
Assembled crown OD	50 – 56 mm	IPI by GLU-0155 Rev 01
Applicator OD	15 ± 0.5 mm	ICI by IC-0587 Rev 01 and

		CMP-01975-002 Rev 00
	Visual inspection	IPI by AC-0276 Rev 01 and AC-0278 Rev 01
Radial force *1	8 ± 3 N	Per TST-037 Rev 01 and ECO – 02006-001
Fatigue Testing	50 cycles	Per TST-037 Rev 01 and ECO – 02006-001
Bonding Strength – Crown foil to sheath	35 N minimum	Per TST-037 Rev 01 and ECO – 02006-001
Bonding Strength – Sheath to connector	35 N minimum	Per TST-037 Rev 01 and ECO – 02006-001
Bonding Strength – Y-adapter to extrusion	35 N minimum	Per TST-037 Rev 01 and ECO – 02006-001
Bonding Strength – Bag to connector	35 N minimum	Per TST-037 Rev 01 and ECO – 02006-001
Withdrawal force *2	45 N maximum	Per TST-037 Rev 01 and ECO – 02006-001

Table II: *Comparative Analysis – bench top.*

S/N	Features and Specifications	Consure 120 SMS	In-dwelling Catheters	Comments
1	Insertion Mechanism	Safe and hygienic applicator available	Unavailable. Device inserted when index finger traverses anatomy	
2	Insertion diameter	Applicator OD: 14 mm	Index Finger + Device: 23 to 30 mm	
3	Indwelling Diverter	Lattice	Inflatable cuff	
	Diverter position	Transverse rectal valve	Anorectal junction	1 - No pain sensation above the rectal valve. 2 – Anchoring at anorectal causing sphincter dysfunction
	Diverter OD	55 mm	53 - 58 mm	
	Radial pressure	4 - 9 cm of H2O	30 – 40 cm of H2O	Above 35 cm of H2O, the body will try to

				expel the in-dwelling diverter thinking its fecal material
	Interference in physiological functioning	No. Lattice is pliable 3 axis	Yes. Applies constant radial pressure	Constant radial pressure manifest pressure necrosis
4	Transit Sheath	Polyurethane 80A	Silicone & TPE	
	Profile Diameter	Less than 7 mm	10 – 15 mm	Large profile diameter causes foreign body sensation to the patient and could lead to sphincter dysfunction
	Wall thickness	0.050 mm	2 mm	Large wall leads to large profile diameter
	Length	370 mm	1500 mm	Long sheath does not enable transfer of formed stool
5	Withdrawal Mechanism	Integrated collapsing system	Deflated using inflation device	
	Collapsed Diameter	17 mm	20 – 30 mm	
6	Odor proof	Yes	Not during bag exchange	
7	Gas release valve	Yes Charcoal Filter	No	Lack of flatus release valve can cause the collection bags to bulge

Substantial Equivalency

A summary of the equivalence between the *Consure 120 SMS* and the predicate device is given in the following table.

Comparison Table of New and Predicate Device

Parameter	Consure 120 SMS	DigniShield™ Stool Management System
Intended Use	Fecal management	Fecal management
Intended Users	Bedridden patients	Bedridden patients
Indications for Use	*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*	*The Bard® DigniShield™ Stool Management System is intended for fecal management by diverting and collecting liquid or semi-liquid stool to minimize skin contact in bedridden patients."*
Patient Population	Adults only	Adults only
Environment of Use	Hospitals, nursing homes	Hospitals, nursing homes
Condition of Use	Single Use	Single Use
Period of Usage	5 days	29 days
Expanded OD	55 mm	55 mm
Self-sealing upon removal?	Yes	Yes
Detachable collection device?	Yes	Yes
Irrigation port	Yes	Yes
Retrieval by	Collapse of crown	Deflation
Closed waste bag volume	Approximate = 1 liter	Approximate = 1 liter
Port	Side catheter connector port	Top catheter connector port
Filter	Charcoal filter	Charcoal filter
Materials		
Catheter	Urethane based TPU that cushions SS 304 wire form lattice	Styrene-based TPE
Collection bag	Urethane based TPU	Styrene-based TPE
Sterility	Supplied non-sterile, disposable, single patient use.	Supplied non-sterile, disposable, single patient use.

Based on the comparison of intended use, indications for use, and technological characteristics, the Consure SMS 120 is substantially equivalent to the Bard DigniShield (K102391), with respect to intended use, indications for use, performance and technological characteristics. The Consure SMS 120 raises no new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 26, 2014

Consure Medical Pvt., Ltd.
% Alan Donald, MS, MBA, FRAPS
President
Matrix Medical Consulting, Inc.
11440 West Bernardo Court, Suite 300
San Diego, CA 92127

Re: K133465
Trade/Device Name: Consure 120 SMS™
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: May 26, 2014
Received: May 29, 2014

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Benjamin R. Fisher -S

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

4 Indications for Use Statement

510(k) Number: K133465

Device Name: Consure 120 SMS ™

Indications For Use:

Consure 120 SMS is indicated for fecal management by diverting and collecting liquid or semi-formed stool to minimize skin contact in bedridden patients.

Prescription Use X AND/OR Over-The-Counter Use

(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
2014.06.26 16:14:31 -04'00'