June 16, 2023

Chess Medical Inc.
℅ Christopher Sloan
President
Sloan Regulatory Consulting
322 Hart Road
Gaithersburg, MD 20878

Re: K223890
Trade/Device Name: NAJA Gastrointestinal Catheter
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: FGD
Dated: May 16, 2023
Received: May 16, 2023

Dear Christopher Sloan:

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); 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,

Sivakami Venkatachalam -S

for
Shanil P. Haugen, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K223890

Device Name
NAJA Gastrointestinal Balloon Catheter

Indications for Use *(Describe)*
The NAJA Gastrointestinal Balloon Catheter is intended to administer contrast medium to the small intestine.

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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510(k) Summary
NAJA Gastrointestinal Balloon Catheter

Submitter

Name	Chess Medical
Address	1650 Sherbrooke Street West, Suite 9E Montreal, Quebec H3H 1C9 Canada
Contact Person	Dr. Yen-I Chen
Phone	(514) 291-3154
Email Address	cyen33@gmail.com
Date Prepared	December 23, 2022

Device

Trade Name	NAJA Gastrointestinal Balloon Catheter
Common Name	Gastrointestinal Balloon Catheter
Classification Name	Gastrointestinal Tube and Accessories
Classification Number	21 CFR 876.5980
Product Code	FGD
Regulatory Class	II

Predicate Device

Name [510(k) Number]	Maglinte Enteroclysis Balloon Catheter [K884379]

Device Description

The NAJA Gastrointestinal Balloon Catheter ("NAJA device") is a single-use, single-operator, over-the-wire, double balloon catheter that is compatible with 0.035" guidewires. The device is introduced orally and designed for temporary occlusion of the gastrointestinal (GI) lumen (small intestine), allowing infusion of fluids for enteroclysis studies (i.e., imaging tests of the small intestine). The device is designed to fit inside the working channel of a gastroscope and reaches its intended location by tracking over a 0.035" guidewire.

The NAJA device features a separate hub connector that is attachable and detachable from the catheter. This feature allows removal of the gastroscope from the catheter once the balloons are in the correct location and before the hub connector is attached for balloon inflation and infusion of fluids into the GI lumen. The hub connector is supplied with 1-way stopcocks on the inflation

and infusion ports. The NAJA device is also provided with a 30cc syringe for balloon inflation and infusion of fluids. The balloons are inflated independently using air.

Indications for Use

The NAJA Gastrointestinal Balloon Catheter is intended to administer contrast medium to the small intestine.

Comparison of Intended Use and Technological Characteristics with the Predicate Device

The proposed NAJA device has the same intended use and similar technological characteristics as the Maglinte Enteroclysis Balloon Catheter ("Maglinte Catheter"). The differences in the design between the devices do not raise different questions of safety and effectiveness. The table below summarizes the comparison between the NAJA device and Maglinte Catheter.

Comparison of NAJA Device to Maglinte Catheter

Attribute		NAJA Device (Subject Device)	Maglinte Catheter (Predicate Device)
510(k) Number		To be assigned	K884379
Applicant		Chess Medical	Lafayette Pharmacal
Classification Regulation; Device Class		876.5980 (gastrointestinal tube and accessories); class II	876.5980 (gastrointestinal tube and accessories); class II
Product Code (Device Type)		FGD (Catheter, Retention, Barium Enema With Bag)	FGD (Catheter, Retention, Barium Enema With Bag)
Intended Use / Indications for Use		…intended to administer contrast medium to the small intestine.	…intended to administer contrast medium to the small intestine.
Sterile / Single Use		Yes	Yes
Sterilization Method		Sterile (Ethylene Oxide)	Sterile (Ethylene Oxide)
Principle of Operation		Inflation of one or two compliant balloons for occlusion of the small intestine, followed by infusion of contrast medium in the small intestine, distal to the proximal balloon or in the inter-balloon space.	Inflation of one compliant balloon for occlusion of the small intestine, followed by infusion of contrast medium in the small intestine, distal to the balloon.
Method of Delivery		Oral insertion, through a compatible working channel (≥ 3.7 mm) of a gastroscope.	Nasal or oral insertion.
Balloons	Number of Balloons	Two	One
	Balloon Inflation Media	Air	Air
	Balloon Diameter	20mm – 50mm	30 mm

Attribute		NAJA Device (Subject Device)	Maglinte Catheter (Predicate Device)
	Balloon Length	36 mm – 48 mm	28 mm
	Inflation Volume	8 ml – 76 ml	15 ml
	Balloon Material	Polyurethane	Latex
Marker Bands	Number of Marker Bands	Five (1) Distal tip, (4) proximal and distal ends of the two balloons	One (1) Distal tip
	Marker Band Length	Distal tip – 4 mm Proximal/Distal balloon ends – 2 mm	Distal tip – 5 mm
	Marker Band Material	Polyether Block Amide (Pebax®) 5533 SA 01 MED w/ Tungsten 80%	Metallic (material unknown)
Shaft	Working Length	260 cm	155 cm
	Number of Layers	Two Interior – Multi-Lumen Extrusion Exterior – Braided Shaft Extrusion	One Bi-Lumen Extrusion
	Number of Lumens	Four (1) Guidewire lumen (1) Infusion lumen (2) Individual balloon inflation lumens	Two (1) Guidewire lumen, doubles as infusion lumen (1) Balloon inflation lumen
	Number of Inflation Exit Ports	Two One inflation exit port per balloon	Two Two inflation exit ports to inflate a single balloon
	Number of Infusion Exit Ports	Three In between the two balloons	Four Distal to the single balloon
	Materials	Interior – Multi-Lumen Extrusion Polyether Block Amide (Pebax®) Exterior – Braided Shaft Extrusion Polyether Block Amide (Pebax®)	Radiopaque Polyvinyl Chloride
	Outer Diameter	Distal 30cm (Multi-Lumen Extrusion) Outer Diameter: 7.5 Fr Proximal 206cm (Braided Shaft Extrusion) Outer Diameter: 10 Fr	Outer Diameter: 13 Fr
	Distal Tip	Open lumen at distal tip, guidewire can advance	Closed distal tip, guidewire cannot advance
	Proximal End	Enclosed within a removable hub	Enclosed within a permanent hub

Attribute		NAJA Device (Subject Device)	Maglinte Catheter (Predicate Device)
Proximal Hub	Detachable	Yes Able to attach/detach proximal hub to/from proximal end of shaft	No Permanently fixed to proximal end of shaft
	Number of Ports	Four (1) Guidewire port (1) Infusion port (2) Individual balloon inflation ports	Two (1) Guidewire port, doubles as infusion port (1) Balloon inflation port
	Mechanism to maintain inflation volume	One-way Stopcock	Check Valve
Guidewire Compatibility		0.035in	0.065in

Biocompatibility Testing

The following biocompatibility testing was performed on the NAJA device.

Biocompatibility Test	Acceptance Criteria Origin	Result	Conclusion
Cytotoxicity Study Using the ISO Elution Method	ISO 10993-5: 2009, Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity	The test article extract showed no evidence of causing cell lysis or toxicity. The test article extract met the requirements of the test since the grade was less than a grade 2 (mild reactivity).	**Pass**
ISO Intracutaneous Study	ISO 10993-23: 2021, Biological Evaluation of Medical Devices – Part 23: Tests for irritation	The test article met the requirements of the test since the difference between each test article extract overall mean score and corresponding control extract overall mean score was 0.0 and 0.0 for the SC and SO test article extracts, respectively.	**Pass**
ISO Maximization Sensitization Study	ISO 10993-10: 2021, Biological Evaluation of Medical Devices – Part 10: Tests for skin sensitization	The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig maximization test.	**Pass**

Bench and Performance Testing

The following bench and performance testing were conducted on the NAJA device.

Design Verification Test	Specification	Test Result
Package Performance Testing		
Legibility of Markings	IFU, pouch label, and carton label are legible.	**Pass**

Design Verification Test	Specification	Test Result
Seal Width	Pouch seal width is ≥ 0.19".	**Pass**
Pouch Seal Visual Inspection	Pouch seals are free of channels or other damages that could impair sterility.	**Pass**
Bubble Emission Test	No evidence of leakage through any surface of pouch.	**Pass**
Pouch Seal Strength	Pouch seal can withstand a force ≥ 3.35N over a seal length of 25.4mm.	**Pass**
Pouch Ease of Opening	Pouch is easily opened with gloved hands, while keeping internal contents stable. Components inside pouch are easily removable from backboard.	**Pass**
Component Visual Inspection	Device components are free of damages that could affect performance of product, such as: kinks, cracks, separated components, etc.	**Pass**
Device Performance Testing		
Visual Inspection		
Surface Defects	All surfaces and open channels of device are free of loose foreign matter, pores, cracks, and remainders of tooling agents.	**Pass**
Atraumatic Tip	Distal tip is smooth, rounded, and free from sharp edges.	**Pass**
Atraumatic Infusion Holes	Infusion holes are smooth and free from sharp edges.	**Pass**
Radiopaque Markers	Five (5) markers are present on device.	**Pass**
Dimensional Analysis		
0.035" GW Loading – Front/Back	Device accommodates front- and back-loading of a 0.035" GW.	**Pass**
Proximal Extrusion Dimensions	Dimensions suitable for insertion into hub connector.	**Pass**
10.5Fr Channel Compatibility	Distal 30cm of device fits through a 10.5Fr channel.	**Pass**
Working Length	Device working length is 2360 ± 20mm.	**Pass**
Tip Length	Tip length is 20 ± 2mm.	**Pass**
Scaffold Length	Scaffold length is 120 ± 2mm.	**Pass**
Catheter Outer Diameter	Outer diameter is ≤ 3.5mm for the catheter shaft, balloon welds, distal tip.	**Pass**
Simulated Use		
Number of Balloons and Size	Device has two balloons that can be inflated to a diameter of 50mm.	**Pass**
Hub Connector Detachability	Hub connector is detachable from device and can be attached for fluid delivery.	
Shaft Insertion Feature	Shaft marker is no longer visible once inserted into hub connector.	

<table>
<tr><th>Design Verification Test</th><th>Specification</th><th>Test Result</th></tr>
<tr><td>Gastroscope Compatibility</td><td>Device fits through working channel of gastroscope.</td><td rowspan="4"></td></tr>
<tr><td>Simulated Use Testing</td><td>The device remains functional throughout the lifecycle of one clinical procedure.</td></tr>
<tr><td>Unique Hub Connector Identification</td><td>Proximal terminations of hub assembly are appropriately identified. Proximal terminations of the hub assembly are appropriately identified.</td></tr>
<tr><td>Legibility of Device Markings</td><td>Wording on hub assembly labels is legible.</td></tr>
<tr><td colspan="3">Functional Testing</td></tr>
<tr><td>Hub Connector and Hub Assembly Pressure</td><td>Pressure decay specification is met.</td><td>Pass</td></tr>
<tr><td>Balloon Pressure and Crosstalk</td><td>Pressure decay specification is met.</td><td>Pass</td></tr>
<tr><td>Balloon OD/L Ratio – unconfined</td><td>Unconfined balloon shape specification is met.</td><td>Pass</td></tr>
<tr><td>Balloon Diameter and Inflation Volume Relationship</td><td>Relationship between balloon diameter and inflation volume shall be determined.</td><td>Balloon Compliance
<table><tr><th>Volume [mL]</th><th>OD [mm]</th></tr><tr><td>9</td><td>20</td></tr><tr><td>20</td><td>30</td></tr><tr><td>44</td><td>40</td></tr><tr><td>76</td><td>50 (MAX)</td></tr></table></td></tr>
<tr><td>Balloon OD/L Ratio – confined</td><td>Confined balloon shape specification is met.</td><td>Pass</td></tr>
<tr><td>Inflation Time</td><td>Injection of 30mL of air in ≤ 4s.</td><td>Pass</td></tr>
<tr><td>Deflation Time</td><td>Removal of 30mL of air in ≤ 17s.</td><td>Pass</td></tr>
<tr><td>Infusion Time</td><td>Infusion of 30mL of water in ≤ 19s.</td><td>Pass</td></tr>
<tr><td>Channel Occlusion</td><td>Device is able to occlude channels 20-50mm.</td><td>Pass</td></tr>
<tr><td colspan="3">Destructive Testing</td></tr>
<tr><td>Rated Burst Volume</td><td>Balloons have a rated burst volume (RBV) ≥ 81.5mL.</td><td>Pass</td></tr>
<tr><td>Bend Radius</td><td>No shaft kink and/or fracture when wrapped 180° around a 20mm bend radius.</td><td>Pass</td></tr>
<tr><td>Shaft Buckling Force</td><td>Shaft buckle force specification is met.</td><td>Pass</td></tr>
<tr><td>Hub to Shaft Slip Force</td><td>Hub connector slip force specification is met.</td><td>Pass</td></tr>
<tr><td>Tensile – Proximal Shaft to Extrusion</td><td>Tensile force of proximal shaft to extrusion is ≥ 15N.</td><td>Pass</td></tr>
<tr><td>Tensile – Distal Shaft to Extrusion</td><td>Tensile force of distal shaft to extrusion is ≥ 15N.</td><td>Pass</td></tr>
</table>

Design Verification Test	Specification	Test Result
Tensile –Extrusion at Scaffold	Tensile force of scaffold shall be ≥ 15N.	**Pass**
Shear – Balloon Distal Neck	Shear force of distal balloon neck to extrusion bond is ≥ 15N.	**Pass**
Peel – Balloon Proximal Neck	Peel force of proximal balloon neck to extrusion bond is ≥ 15N.	**Pass**
Tensile – Extension Tube to Hub Connector	Tensile force of extension tube to hub connector bond is ≥ 15N.	**Pass**
Tensile – Luer to Extension Tube	Tensile force of luer to extension tube bond is ≥ 15N.	**Pass**

Conclusions

The NAJA Gastrointestinal Balloon Catheter (subject device) is substantially equivalent to the legally marketed Maglinte Enteroclysis Balloon Catheter (predicate device) for administering contrast medium to the small intestine. The two devices have the same intended use and similar technological characteristics. The differences in the design between the devices do not raise different questions of safety and effectiveness. The results of biocompatibility testing confirm that the materials of construction of the NAJA device are safe, and the results of bench and performance (design verification) testing demonstrate that the NAJA device can function adequately in accordance with its intended use.

Chess Medical Inc. concludes that the NAJA Gastrointestinal Balloon Catheter (subject device) is substantially equivalent to the Maglinte Enteroclysis Balloon Catheter (predicate device).