October 11, 2019

Cook Incorporated
Irasema Rivera, M.A., M.P.H
Regulatory Affairs Specialist
750 Daniels Way
P.O. Box 489
Bloomington, IN 47404

Re: K190084
Trade/Device Name: McLean-Ring Nasojejunal Feeding Tube Set
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: September 6, 2019
Received: September 9, 2019

Dear Irasema Rivera:

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,

for
Martha W. Betz, Ph.D.
Acting 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)*
K190084

Device Name
McLean-Ring Nasojejunal Feeding Tube Set

Indications for Use *(Describe)*
The McLean-Ring Nasojejunal Feeding Tube Set is intended for enteral feeding and medication in adult and pediatric populations. The device is intended to be used in the treatment of the following pediatric subgroups: children and adolescents.

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

K190084
McLean-Ring Nasojejunal Feeding Tube Set
21 CFR §876.5980
Date Prepared: 11 October 2019

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact:	Irasema Rivera
Secondary Contact:	Karthik Pillai
Email:	RegSubmission@CookMedical.com
Contact Phone Number:	(812) 335-3575 x105166
Contact Fax number:	(812) 332-0281

Device Information:

Trade Name:	**McLean-Ring Nasojejunal Feeding Tube Set**
Device Common Name:	Gastrointestinal tube and accessories
Classification Regulation:	21 CFR §876.5980, Product Code KNT
Device Class:	Class II,
Classification Panel:	Gastroenterology/Urology

Predicate Device:

The McLean-Ring Enteral Feeding Tube Set is substantially equivalent to the following device: Tiger 2 Self-Advancing Nasal Jejunal Feeding Tube (K160509, Cook Incorporated) cleared on May 18, 2017.

Device Description:

The McLean-Ring Nasojejunal Feeding Tube Set is composed of a feeding tube and wire guide. The feeding tube is made of a 9.5 French polyurethane tube. The feeding tube is available in 130 centimeters only, measured from the distal tip to the proximal hub. The distal end of the feeding tube features six sideports. The distal tip of the feeding tube is open with a smooth round finish. A 0.650-inch long stainless steel weight is fit outside the distal end of the feeding tube and is completely covered with a shrink tube, forming 0.180-inch outer diameter over the weight. The proximal end of the feeding tube features a hub with a cap that is made of polyurethane.

The wire guide is made of stainless steel in a 0.038-inch diameter. The wire guide is 275 centimeters long. In addition, the entire length of the wire guide is coated with PTFE. The distal end of the wire guide is straight but flexible.

The subject device, McLean-Ring Nasojejunal Feeding Tube Set, may be introduced directly when there is adequate peristalsis and no gastric outlet obstruction. Alternatively, the feeding tube may be passed over a wire guide. The feeding tube is intended to be indwelling up to 30 days and is for one-time use.

Indications for Use:

The McLean-Ring Nasojejunal Feeding Tube Set is intended for enteral feeding and medication in adult and pediatric populations. The device is intended to be used in the treatment of the following pediatric subgroups: children and adolescents.

Comparison to Predicate Device:

The subject device, McLean-Ring Nasojejunal Feeding Tube Set, and the predicate device, the Tiger 2 Self-Advancing Nasal Jejunal Feeding Tube (K160509), are substantially equivalent in that these devices have a similar intended use, technological characteristics, placement location, indwell time, sterilization method, and packaging. The subject device and predicate device similarly establish an enteral delivery for feeding and medication. The subject device and predicate device have identical characteristics including the number of sideports on the distal end of the catheter and rounded distal tip. The subject device and predicate device pass through the patient's oropharynx before descending the gastrointestinal track to the intended access site. The predicate device's access sites are the stomach or the small bowel; the subject device's access sites are the pylorus or the duodenum, which lie between or are part of the stomach and small bowel.

The differences between the subject and the predicate device including the materials of construction, catheter dimensions, distal tip features, mode of operation, and intended patient population do not raise any new issues of safety and/or effectiveness.

Similarities and differences in technological characteristics are captured in the substantial equivalence comparison of the subject device, McLean-Ring Nasojejunal Feeding Tube Set, and the predicate device, Tiger 2 Self-Advancing Nasal Jejunal Feeding Tube, which is provided in Table 1.

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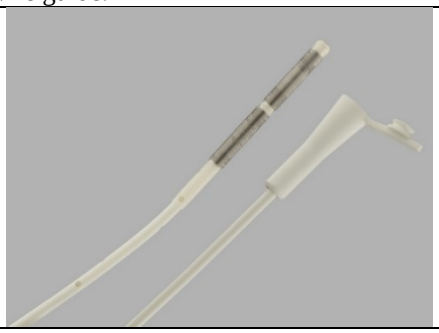
Table 1: Substantial Equivalence

		Tiger 2 Self-Advancing Nasal Jejunal Feeding Tube (K160509)	McLean-Ring Nasojejunal Feeding Tube Set Subject Device
Regulation Number		876.5980	876.5980
Product Code		KNT	KNT
Classification		II	II
Intended Use		Intended to provide short-term enteral access for delivery of nutrition and/or medications to the small bowel in patients older than 12 years old	Intended for enteral feeding and medication in adult and pediatric populations. The device is intended to be used in the treatment of the following pediatric subgroups: children and adolescents
Mode of Operation		Flaps allow catheter to be pulled into the stomach or small bowel by peristalsis from the patient's nose or mouth	Advance the catheter through the external naris through the pylorus and duodenum to the level of ligament of Treitz with the aid of peristalsis, or by introduction over a wire guide.
Device Picture			
Catheter	**Length**	153 cm	130 cm
	Outer Diameter	14 Fr	9.5 Fr
	Shaft Material	Polyether-Urethane	Polyurethane
	Hub Material	Polyvinyl chloride (PVC)	Polyurethane
	Hub Inner Diameters	0.255-inch tapers to 0.150-inch in 0.185-inch length	0.313-inch tapers to 0.135-inch in 0.537-inch length
	Distal Tip	Rounded, no endhole, sideports, no weight	Rounded, endhole, sideports, distal weight
	Sideports	6	Identical
Maximum Indwell		Up to 30 days	Identical
Device for One-Time Use		Yes	Identical
Sterilization, SAL		ETO, 10^{-6}	Identical
Packaging		Tyvek peel-open pouch	Identical

Technological Characteristics:

The subject device, McLean-Ring Nasojejunal Feeding Tube Set, was subjected to the following applicable testing to assure reliable design and performance under the specified testing parameters:

Bench Testing

- Dimensional, Compatibility and Visual Analysis (Zero Time and Accelerated Aged)
- Flow Rate Testing (Zero Time and Accelerated Aged)
- Resistance to Liquid Leakage Under Positive Pressure (Zero Time and Accelerated Aged)
- Kink Resistance (Zero Time and Accelerated Aged)
- Corrosion Testing (Zero Time and Accelerated Aged)
- Tensile Testing (Zero Time and Accelerated Aged)
- MRI Testing (*Magnetically Induced Displacement Force, Magnetically Induced Torque, RF-Induced Heating, Image Artifact*) (Zero Time)
- Radiopacity Testing (Zero Time)
- ISO 80369-1: Non-Interconnectability Testing (Zero Time)
- Wire Guide Puncture Evaluation (Zero Time and Accelerated Aged)

Biocompatibility Testing:

Per ISO 10993-1 and FDA guidance, testing for cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, subchronic toxicity, implantation, and material-mediated pyrogenicity were performed to ensure the biocompatibility of the subject device.

Clinical Evidence:

Published literature was evaluated as supporting evidence that the subject device is appropriate for use in children (2 years and older) and adolescents. Six articles provided clinical evidence on safety and performance of using 6 French, 8 French, or 10 French post-pyloric feeding tubes in pediatric patients. The studies, number of patients, description of the patients/subjects, and a summary of the safety and/or effectiveness data as it pertains to adverse effects and complications reported in the studies is summarized in Table 2.

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Table 2: Clinical literature

<table>
<tr><th>Study
(Study type)</th><th>Number of pediatric patients</th><th>Patient Age</th><th>Tube Size</th><th>Safety Data Associated with Use of Feeding Tube</th></tr>
<tr>
<td>Lyman B., Kemper C., Northington L., Yaworski J.A., Wilder K., Moore C., Duesing L.A., Irving S. Use of Temporary Enteral Access Devices in Hospitalized Neonatal and Pediatric Patients in the United States. Journal of Parenteral and Enteral Nutrition. 2014, 40:4 (574-580). (Prevalence study)</td>
<td>1435
233
120
132</td>
<td>
<table>
<tr><th>Weight (kg)</th><th>Estimated age (months)*</th></tr>
<tr><td>< 5</td><td>< 4</td></tr>
<tr><td>5 to < 10</td><td>4 to < 22</td></tr>
<tr><td>10 to < 20</td><td>22 to < 96</td></tr>
<tr><td>>20</td><td>> 96 (8 years)</td></tr>
</table>
</td>
<td>
<table>
<tr><th>Average Tube Size (Fr)</th><th>Smallest Tube Size (Fr)</th></tr>
<tr><td>6</td><td>4</td></tr>
<tr><td>7</td><td>5</td></tr>
<tr><td>8</td><td>5</td></tr>
<tr><td>9</td><td>5</td></tr>
</table>
</td>
<td>No adverse events due to procedure or devices were reported in this study</td>
</tr>
<tr><td>Clifford P., Ely E., Heimall L. Bedside Placement of the Postpyloric Tube in Infants. Advances in Neonatal Care. 2017, 17:1 (19-26). (Prospective cohort)</td><td>1435</td><td>Mean 40.5 weeks/</td><td>6 French</td><td>Lower success rate of placement in infants with congenital diaphragmatic hernia (CDH)</td></tr>
<tr><td>Koot et al. Electromagnetic-guided postpyloric tube placement in children: pilot study of its use as a rescue therapy. European e-Journal of Clinical Nutrition and Metabolism 2011, 6:2 (e74-e76). (Retrospective case series)</td><td>233</td><td>Median 7.5 years (range: 1-month to 14 year)</td><td>8, 10 French</td><td>No adverse events occurred, and the tubes were well tolerated.</td></tr>
<tr><td>October and Hardart. Successful placement of postpyloric enteral tubes using electromagnetic guidance in critically ill children. Pediatric Critical Care Medicine 2009, 10:2 (196-200). (Prospective cohort)</td><td>120</td><td>Median 3.2 years (range: 2-month to 24 years)</td><td>8, 10 French</td><td>No acute complications observed during the trial period</td></tr>
<tr><td>Iglesias et al. Enteral nutrition in critically ill children: are prescription and delivery according to their energy requirements? Nutrition in Clinical Practice 2007, 22:2 (233-239). (Prospective cohort)</td><td>132</td><td>Mean 8.2 month (range: 0 to 13.5 years)</td><td>Article does not mention the size of feeding tube being used in patients.</td><td>Accidental feeding tube removal (27%).</td></tr>
</table>

Table 2: Clinical literature (continued)

Study (Study type)	Number of pediatric patients	Patient Age	Tube Size	Safety Data Associated with Use of Feeding Tube
Pobiel, R. S., Bisset 3rd, G. S., & Pobiel, M. S. Nasojejunal feeding tube placement in children: four-year cumulative experience. Radiology, 1994, 190:1 (127-129).	232	Mean 3.5 years (range: 1 week to 24 years)	8 French	3% unsuccessful due to malrotation, CDH, gaseous distension, or hypertrophic pyloric stenosis
Cone L.C., Gilligan M.F., Kagan R.J., Mayes T., Gottschlich M.M. Enhancing patient safety: The effect of process improvement on bedside fluoroscopy time related to nasoduodenal feeding tube placement in pediatric burn patients. Journal of Burn Care and Research 2009, 30:4 (606-611).	2161 fluoroscopic assisted tube placements. Number. Total number patients not reported.	Age range not reported, although the study was conducted on pediatric burn patients.	8 French	99 % success rate. No adverse events reported

* Age estimated based on CDC weight chart for girls at the 5th percentile.

These data do not identify additional potential adverse events that are not covered in the proposed IFU of the subject device. The clinical literature summarized in Table 2 provides supporting evidence that the subject device is appropriate for use in children (2 years and older) and adolescents and raises no new question of safety and/or effectiveness.

Conclusion:

The results of these tests confirm that the McLean-Ring Nasojejunal Feeding Tube Set meets the design input requirements based on the intended use and support the conclusion that this device does not raise new questions of safety and/or effectiveness and is substantially equivalent to the predicate device, the Tiger 2 Self-Advancing Nasal Jejunal Feeding Tube (K160509, Cook Incorporated).