January 3, 2020

Intuit Medical Products, LLC
Jack Griffis
Vice President, R&D
6018 Eagles Rest Trail
Sugar Hill, Georgia 30518

Re: K181546
Trade/Device Name: Dillard Nasal Balloon Catheter
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, Nose, And Throat Manual Surgical Instrument
Regulatory Class: Class I, reserved
Product Code: QGK
Dated: October 7, 2019
Received: October 8, 2019

Dear Jack Griffis:

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 Michael J. Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental 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)*
K181546

Device Name
Dillard Nasal Balloon (DNB) Catheter

Indications for Use *(Describe)*
The Dillard Nasal Balloon (DNB) Catheter is an instrument intended to provide increased intranasal space to facilitate access for endonasal and transnasal procedures and/or temporarily address nasal obstruction by displacing the inferior turbinate and lower nasal septum.

The Dillard Nasal Balloon (DNB) Catheter is intended for use in ages 17 years or older.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

510(k) Number: K181546

Date Revised: December 31st, 2019

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

A. Submitter:
Intuit Medical Products (IMP), LLC
6018 Eagles Rest Trail
Sugar Hill, Georgia 30518

B. Company Contact:
Jack Griffis
Vice President, Research & Development
(404) 583-6889 (direct)
jgriffis@intuitmedicalproducts.com

C. Device Information:
Trade Name: Dillard Nasal Balloon Catheter (*DNB*)
Common Name: Balloon, Nasal Airway

D. Classification: Ear, nose, and throat manual surgical instruments
QGK, 21 CFR 874.4420
Class I

E. Predicate Devices:
Acclarant RELIEVA TRACT™ Balloon Dilation System, K183090

Additional Reference Devices (for technological comparison ONLY):
ECONOM™ speculum for ENT applications, K925754
Dillard Sinuplasty Balloon Catheter (*DSB*), K143738
Dillard Airway Dilatation System (*DAS*), K153484

F. Physical Description:
The Dillard Nasal Balloon (*DNB*) Catheter has a total length of either 25cm or 100cm and is available in balloon diameters from 5mm to 12mm and balloon lengths of 20mm and 40mm. The balloon component of the catheter has radiopaque markers to assist with radiographic positioning (as applicable). The proximal end of the device is a common catheter design consisting of a plastic hub and strain relief. The hub is used to inflate the balloon and the luer connector integrated into the hub is compatible with standard inflation devices. A second lumen within the catheter, intended for guidewire use, extends through the central lumen back to the proximal hub and through the distal tip. All catheters and accessories are supplied sterile and intended for single use.

NOTE: the proposed device is identical to those previously cleared under K143738 and K153484 with the exception of the indication for use.

G. Indications for Use:

The Dillard Nasal Balloon Catheter is an instrument intended to provide increased intranasal space to facilitate access for endonasal and transnasal procedures and/or temporarily address nasal obstruction by displacing the inferior turbinate and lower nasal septum.

The Dillard Nasal Balloon Catheter is intended for use in ages 17 years or older.

H. Comparison of Characteristics / Performance Testing / Substantial Equivalence:

The *DNB* Catheter is substantially equivalent to the predicate devices in intended use, indications for use or fundamental scientific technology and important performance specifications. Refer to the Table below for a summary:

Characteristic	**Proposed Device** (Dillard Nasal Balloon Catheter, K181546)	**Predicate Device** (Acclarent TRACT™ Balloon Catheter, K183090)	**Reference Device** (Single use speculum for ENT applications, K925754)
Indication for Use	*"…an instrument intended to provide increased intranasal space to facilitate access for endonasal and transnasal procedures and/or temporarily address nasal obstruction by displacing the inferior turbinate and lower nasal septum"*	*"…an instrument intended to provide increased intranasal space to facilitate access for endonasal and transnasal procedures and/or temporarily address nasal obstruction by displacing the inferior turbinate and lower nasal septum"*	*Speculum (ENT) – Procode EPY: …a device intended to be inserted into a body cavity to aid observation. It is either nonilluminated or illuminated and may have various accessories*
Classification Name	*Ear, nose, and throat manual surgical instrument*		*Speculum, ENT*
Product Code	*QGK*		*EPY*
Classification Section	*21 CFR 874.4420*		*21 CFR 878.1800*
Principle of Operation	*Operates on the principle of hydraulic pressurization applied through an inflatable balloon attached to the distal end to mechanically dilate internal passages*		*Operates on the principle of mechanical leverage applied through a rigid body and a fulcrum for leverage to expand internal passages*
Materials	Various medical grade polymers and metal alloys – refer to Table A, page 38 of the submission		Various medical grade polymers and metal alloys
Single Patient Use	*Yes*	*Yes*	*Yes*
Direct Patient Contact	*Yes*	*Yes*	*Yes*
Balloon Diameter and Length	*5mm X 20mm & 40mm* *6mm X 20mm & 40mm* *7mm X 20mm & 40mm* *8mm X 20mm & 40mm* *9mm X 20mm & 40mm* *10mm X 20mm & 40mm* *11mm X 20mm & 40mm* *12mm X 20mm & 40mm*	*5mm x 24mm* *7mm x 24mm* *8.5mm x 24mm* *10mm x 40mm* *12mm x 40mm* *14mm x 40mm* *16mm x 40mm*	*N/A*

Characteristic	Proposed Device (Dillard Nasal Balloon Catheter, K181546)	Predicate Device (Acclarent TRACT™ Balloon Catheter, K183090)	Reference Device (Single use speculum for ENT applications, K925754)
Maximum Inflation Pressure	*10 – 12ATM*	*8 – 16ATM*	*N/A*
Flexible Shaft	*Yes*	*Yes*	*No – rigid body*
Catheter Length	*25CM and 100CM*	*45CM*	*N/A*
Sterilization Method	*100% Ethylene Oxide gas*		
Packaging	*Pouch, Protective Tube, Stylet*		*Pouch*

In addition, the device was subjected to the following performance tests to support the assertion of substantial equivalence*:*

- Dimensional specifications
- Joint separation strength
- Compatibility with (standard) accessories
- Balloon burst pressure
- Inflation and deflation times
- Balloon cycle fatigue in simulated use (simulated nasal septum and surrounding support structures)
- Simulated use in cadavers
- Biocompatibility Testing in compliance with the ISO 10993
- Sterilization Validation in compliance with the ISO 11135
- Packaging Integrity and Transportation Validation in compliance with the ISO 11607 and ISTA Part 2A
- Shelf life testing to 3 years real-time equivalent in compliance with the ASTM F1980
- NOTE: no clinical testing was required to establish safety and efficacy

I. Conclusion from Clinical and Non-Clinical Testing:

No new questions of safety or effectiveness were identified for the *Dillard Nasal Balloon* Catheter compared to the predicate. Performance testing demonstrated the DNB performs as intended and is as safe and as effective as the predicate device. Therefore, the DNB is considered substantially equivalent to the predicate device.

Jack Griffis
Vice President, Research & Development

IMP Intuit Medical Products, LLC

6018 Eagles Rest Trail
Sugar Hill, GA 30518
404-583-6889 phone