



September 30, 2026

Danumed Medizintechnik GmbH
Helena Bastian
Head of QM/ RA
Stadthof 18
Regensburg, 93059
Germany

Re: K262038
Trade/Device Name: danumed StomaMeter
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: Class II
Product Code: KNT
Dated: September 2, 2026
Received: September 2, 2026

Dear Helena Bastian:

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 (the 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 available 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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding

When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

STEPHANIE COLE -S

for

Anthony C. Lee, Ph.D., M.B.A

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K262038

?

Please provide the device trade name(s).

?

danumed StomaMeter

Please provide your Indications for Use below.

?

The danumed StomaMeter determines the length of an already existing and healed stoma tract, in order to support the selection of the appropriate length of a gastrostomy button.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

?

Please select the age group(s) for which the device(s) is to be used.

☐ Neonates/Newborns (Birth to < 29 days old)

☒ Infants (29 days old to < 2 years old)

☒ Children (2 years old to < 12 years old)

☒ Adolescents (12 years old to < 22 years old)

☒ Adults (22 years old and greater)

?

510(k) #: K262038

510(k) Summary

Prepared on: 2026-09-02

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	danumed Medizintechnik GmbH
Applicant Address	Stadtamhof 18 Regensburg 93059 Germany
Applicant Contact Telephone	049 94189058882
Applicant Contact	Mrs. Helena Bastian
Applicant Contact Email	hb@danumed.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	danumed StomaMeter
Common Name	Gastrointestinal tube and accessories
Classification Name	Tubes, Gastrointestinal (And Accessories)
Regulation Number	876.5980
Product Code(s)	KNT

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K152246	Aquarius Stoma Measuring Device	KNT

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The danumed StomaMeter® is a sterile, single-use stoma measurement device intended to determine the length of an established and fully healed gastrostomy stoma tract to support the selection of an appropriately sized low-profile gastrostomy button.

The device is inserted through the existing stoma into the stomach. A distal retention balloon is inflated via a Luer valve to secure the device against the gastric wall, and the stoma length is determined using millimeter scale markings on the shaft in combination with a movable external measuring plate. After measurement, the balloon is deflated and the device is removed.

The device consists of a flexible shaft with scale markings, a retention balloon, a movable measuring plate, and a proximal Luer valve. It has short-term contact with mucosal tissue and skin and is intended for use by healthcare professionals in clinical settings.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The danumed StomaMeter determines the length of an already existing and healed stoma tract, in order to support the selection of the appropriate length of a gastrostomy button.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The danumed StomaMeter® is substantially equivalent to the predicate device Aquarius™ Stoma Measuring Device (K152246), cleared on June 21, 2016. Both devices are intended to measure the length of an established gastrostomy stoma tract to support the selection of an appropriately sized gastrostomy button.

The proposed device and the predicate device have the same intended use, similar labeling, and are both sterile, single-use devices intended for use in hospitals or healthcare facilities for adult and pediatric patients. Both devices have comparable technological characteristics, including a silicone shaft with an inflatable retention balloon, a movable external measuring plate, and a Luer connection

for balloon inflation. Minor differences in design, such as the closure mechanism of the unused lumen, do not affect the intended use, performance, or safety of the device.

Based on the similarities in intended use, design, materials, and performance testing, the danumed StomaMeter® is considered substantially equivalent to the identified predicate device.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

Regarding the technological characteristics of the predicate compared to the subject device one difference in design can be stated: The closure mechanism of the two devices are slightly different. The danumed StomaMeter includes a separate sealing plug on the proximal end of the device, whereas in Degania's SMD the closure is attached to the shaft of the SMD. However, the unused lumens of both devices can be closed, so that this difference does not affect the performance or safety of the device in any way. For this reason, the difference in design is neglectable and does not pose a technological difference. There are no other differences regarding technology: Similar materials were used for both products and similar performance testing was conducted.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Bench testing was conducted to verify the functional performance and design characteristics of the device. Testing included verification of measurement accuracy, balloon performance (integrity, burst volume, inflation system performance, and concentricity), mechanical strength of device connections, dimensional verification, and evaluation of marking legibility and durability. Testing was performed in accordance with applicable sections of the FDA-recognized standard ISO 20695:2020 (Enteral feeding systems – Design and testing) and relevant internal test methods. All testing met predefined acceptance criteria and demonstrated that the device performs as intended.