October 6, 2025

Coloplast Corp
Preeti Jain
Principal Regulatory Affairs Specialist
1601 West River Road North
Minneapolis, Minnesota 55411

Re: K252140
Trade/Device Name: Heylo™ System
Regulation Number: 21 CFR 876.5900
Regulation Name: Ostomy Pouch And Accessories
Regulatory Class: Class I
Product Code: EXB, EZQ, EZS
Dated: July 7, 2025
Received: July 8, 2025

Dear Preeti Jain:

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.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

ANTHONY LEE -S

Anthony Lee, PhD, MBA
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K252140

Device Name

Heylo™ System

Indications for Use *(Describe)*

Heylo™ System is indicated to allow detection of ostomy appliance leakage for people with an ileostomy or colostomy, giving them an opportunity to take preventative measures. Heylo™ System is comprised of a protective adhesive barrier with integrated sensors that detect occurrences of leakage of output from the wearer's stoma and a transmitter that translates leakage data and sends notifications to the user's Heylo™ app. Heylo™ System and its components are for individuals with an ostomy 12 years and 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.

510(k) SUMMARY

I. SUBMITTER

510(K) Owner's Name: Coloplast Corp

Name of Contact Person: Preeti Jain

Phone/Fax/Email: Phone: (612) 413-5614
Email: uspj@coloplast.com

Address/Contact: 1601 West River Road North
Minneapolis, MN 55411

Date Prepared: September 8, 2025

II. DEVICE

Trade or Proprietary Name: Heylo™ System

Common or Usual Name: Ostomy pouch and accessories

Classification Name: Collector, Ostomy
(21 CFR section 876.5900)
Product Code(s): EXB,
EZQ, EZS
Device Class: 1

Classification Panel: Gastroenterology-Urology

III. PREDICATE DEVICE

Primary Predicate:	Ostom-I Alert
510(k) Holder:	11 HEALTH AND TECHNOLOGIES LLC
510(k) Number:	K140938

IV. DEVICE DESCRIPTION

Heylo™ System is a leakage notification system designed to monitor for leakage of stoma output in patients with an ileostomy or colostomy. Heylo™ System is comprised of a protective adhesive barrier with integrated sensors that detect occurrences of leakage of output and a transmitter that translates leakage data and sends notifications to the user's Heylo App.

The Heylo™ System is considered an accessory to the ostomy bag/pouch. It is intended to be used together with an ostomy barrier (synonymous with ostomy pouch, ostomy baseplate and bag) and designed for compatibility with most baseplates and supporting products. It can be worn wherever patients normally wear their ostomy appliance.

V. INDICATIONS FOR USE

Heylo™ System is indicated to allow detection of ostomy appliance leakage for people with an ileostomy or colostomy, giving them an opportunity to take preventative measures. Heylo™ System is comprised of a protective adhesive barrier with integrated sensors that detect occurrences of leakage of output from the wearer's stoma and a transmitter that translates leakage data and sends notifications to the user's Heylo app. Heylo™ System and its components are for individuals with an ostomy 12 years and older.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device and predicate both consist of sensors applied to existing ostomy bags/baseplates and provide notifications and other information to the patient via mobile devices and Bluetooth technology to prevent unfortunate spillage and leakage. While the OSTOM-i™ Alert, detects fill volume, the subject device, Heylo™ System, observes potential leakage between the patient's skin and the ostomy bag. The predicate device was selected because it is similar in technology and intended use to the Heylo™ System.

The Heylo™ System is an accessory to an ostomy pouch under the EXB product code. The Heylo™ System accessory sends ostomy bag leakage data via the transmitter to the patient's downloaded app on their iOS or Android device. The information is then reviewed by the patient who can respond by changing their ostomy bag/baseplate as needed. Both devices are ostomy accessories with sensor technology, have comparable intended use, and have technological differences that do not raise different questions of safety and effectiveness.

The Heylo™ System accessory is substantially equivalent to OSTOM-i™ Alert (K140938). A comparison of the devices is presented in Table 1.

Table 1: Comparison of Technological Characteristics

Device Characteristic	**Subject Device** Coloplast Heylo™ System	**Predicate Device** 11 Health Technologies, LLC OSTOM-i™ Alert (K140938)
Device Trade or Proprietary Name	Heylo™ System	OSTOM-i™ Alert
K Number	TBD – Subject of this Submission	K140938
Regulation Number	21 CFR 876.5900 510(k) Exempt	21 CFR 876.5900 510(k) Exempt
Classification Name / Regulation Description	Ostomy pouch and accessories	Ostomy pouch and accessories
Product Code	EXB	EXB
Secondary Product Code	EZQ, EZS	EZQ, EZS
Class	Class I	Class I
Review Panel	Gastroenterology/Urology	Gastroenterology/Urology
Indications for Use	Heylo™ System is indicated to allow detection of ostomy appliance leakage for people with an ileostomy or colostomy, giving them an opportunity to take preventative measures. Heylo™ System is comprised of a protective adhesive barrier with integrated sensors that detect occurrences of leakage of output from the wearer's stoma and a transmitter that translates leakage data and sends notifications to the user's Heylo app. Heylo™ System and its components are for individuals with an ostomy 12 years and older.	The OSTOM-i™ Alert is intended to be used as an accessory to any ostomy bag by monitoring the filling of the bag which information is sent via Bluetooth to a tablet computer to warn healthcare personnel when a patient's bag is close to being full. The Tablet computer automatically captures the data as to the volume and timing of output for each patient. The sensor-based OSTOM-i™ Alert attaches to any ostomy bag and is able to send messages via Bluetooth to a mobile app to warn patient when ostomy bag is close to being full. The sensor-based OSTOM-i™ Alert is intended to be used by the patient outside of the hospital environment. The OSTOM-i™ Alert is indicated for all patient populations.
Use Environment	Hospital and home use	Hospital and home use
Patient Population	Patients aged 12 years and above using ostomy bags	All patients using ostomy bags
Disposable	Single patient use, with reusable components (transmitter, charger, and cable)	Single patient use
Device Design: Collection	Ostomy bag with portable sensor attachment to transmitter	Ostomy bag with portable sensor attachment
Device Design: Status	Notification via sensor detection, interpreted and communicated via Bluetooth to a dedicated mobile app	Visual and alert via sensor detection which sends fill alert to a dedicated tablet computer

VII. PERFORMANCE DATA

The following testing data was provided in support of the substantial equivalence determination.

Biocompatibility Testing

Biocompatibility testing was conducted based upon ISO 10993-1 (2018): Biological evaluation of medical devices – Part 1: "Evaluation and testing within a risk management process" and FDA Guidance for Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process" - Guidance for Industry and Food and Drug Administration Staff – September 2023.

Non-Clinical Bench Testing

Non-clinical bench testing was conducted to support the performance of the subject device for its intended use. Performance testing included:

- Water Absorption
- Peel Strength between Protective Layer and Skin
- Peel Force between Protective Layer and Ostomy Barrier
- Signal Test for Electronic Detection
- Battery Charge Time
- Battery Life
- Usability
- Shelf-life testing
- EMC Testing
- Wireless Testing
- Electrical, Mechanical, and Thermal (EMT) Testing

Performance testing demonstrated the subject device can be used just as safely and effectively as the predicate for the proposed indications for use.

Packaging and Transportation

Packaging and transportation testing included Signal Test for Electronic Detection, Separation Force Measurement, Battery Charge Time, Battery Life, and visual inspection. The testing met the requirements of ASTM D4169, and the Heylo System was verified not to be affected by transportation.

Animal and Clinical Studies

No animal studies or clinical testing were provided to support substantial equivalence between the subject and predicate device.

VIII. CONCLUSIONS

The Heylo™ System has been demonstrated to be substantially equivalent to the primary predicate, OSTOM-I Alert, based on the non-clinical data provided. The test results

demonstrated that the subject device can be used just as safely and effectively as the predicate for the proposed indications for use.