November 16, 2018

11 Health Technologies Limited
Priya Woodun
Regulatory Affairs
The Kinetic Business Centre, Theobald Street
Borehamwood WD6 4PJ
UNITED KINGDOM

Re: K181643
Trade/Device Name: SmartBag (SmartPouch)
Regulation Number: 21 CFR 876.5900
Regulation Name: Ostomy pouch and accessories
Regulatory Class: Class I
Product Code: EXB, EZQ, EZS, LHQ
Dated: September 13, 2018
Received: September 20, 2018

Dear Priya Woodun:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel G. Walter Jr -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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)*
K181643

Device Name
SmartBag(SmartPouch)

Indications for Use *(Describe)*
SmartBag is intended for use inside and out of hospitals for any patient with a diversionary urinary or fecal stoma. It works in conjunction with 11 Health's care management platform known as Alfred. The SmartBag system uses integrated sensors to continuously monitor bag filling and drainage, providing cumulative output data to the patient and clinical team. The system also monitors skin condition, the occurrence of leaks and visual condition of the stoma.

SmartBag's intended use is to help ostomates acclimate to their lifestyle. It works in conjunction with 11 Health's care management platform known as Alfred, designed for patients and medical professionals. The SmartBag system (including the wafer and Hub), offers a continuous ostomy monitoring system, tracks the estimated volumetric filling of the bag and visual condition of the stoma using integrated sensor technology.

The SmartBag Sytem is for adult use only. (22 years and above)

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
807.92(c)

SPONSOR **807.92(a)(1)**

Company Name: 11 Health Technologies
Company Address Kinetic Business Centre
Theobald Street
Borehamwood WD6 4
United Kingdom
Telephone: +44 (0) 20 8387 1308
Contact Person: Priya Woodun
Summary Preparation Date: June 15, 2018

DEVICE NAME **807.92(a)(2)**

Trade Name: SmartBag(SmartPouch)
Common/Usual Name: Ostomy Bag/Pouch
Classification Name: Collector, Ostomy
Regulation Number**:** 21 CFR 876.5900
Regulation Name: Ostomy Pouch and Accessories
Product Code: EXB, EZQ, EZS, LHQ
Device Class: Class I

PREDICATE DEVICE **807.92(a)(3)**

Legally Marketed Equivalent Device

K Number	Product Name	Manufacturer
K140938	Alfred Alert	11 Health and Technologies Limited

REFERENCE DEVICE

Legally Marketed Reference Device

K Number	Product Name	Manufacturer
K150457	AlfaSight 9000 Thermographic System	Alfa Thermodiagnostics, Inc.

Our reference device (Alfasight 9000TM) suggests that skin thermal regulation and skin temperature can be utilized to identify various organ diseases including abnormalities in female breast, peripheral vascular disease, musculoskeletal disorders, extracranial cerebral and facial vascular disease, abnormalities of the thyroid gland, and various neoplastic conditions. Alfasight 9000TM utilizes thermal sensors and measures the subject's skin surface temperature to indicate deeper level organ diseases, while the SmartBag system has NTC thermistors integrated into the wafer to measure the peristomal skin temperature and indicate peristomal skin complication. In summary, there has been medical evidence of utilizing skin temperature for various diagnosis, supporting our hypothesis that peristomal skin temperature may indicate skin complications.

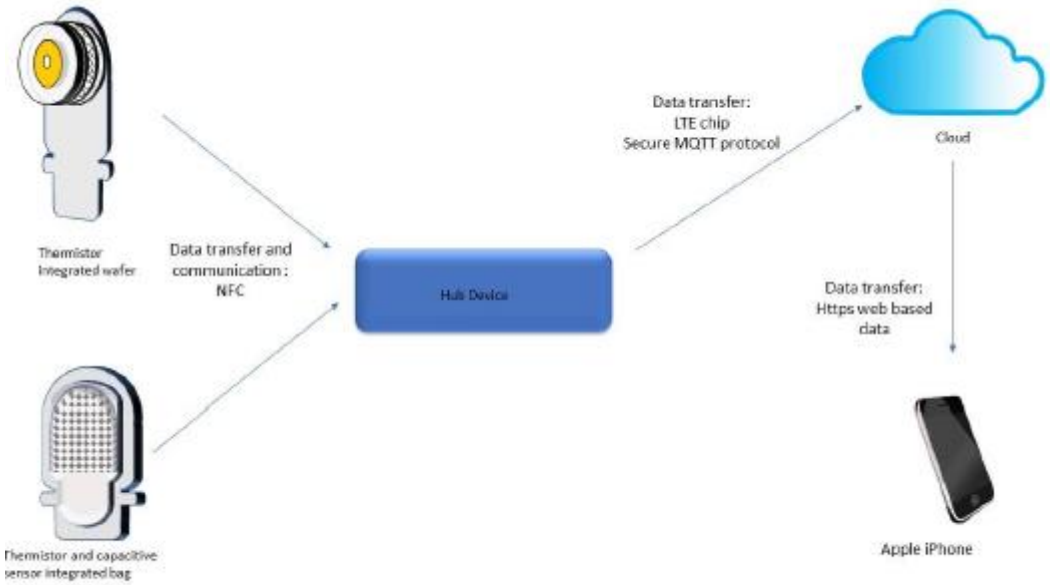
DEVICE DESCRIPTION **807.92(a)(4)**

The SmartBag with integrated thermistors and capacitive sensors can be used in place of a traditional ostomy bag. It notifies patients or medical professionals of any potential leaks around the peristomal skin as well as giving an estimate of the output volume within the bag.

SOFTWARE DESCRIPTION

Alfred software is a companion software suite for SmartBag. It consists of Alfred mobile app and Alfred hospital app. Alfred mobile app is a companion application for mobile phone. The application provides SmartBag user easy access to bag status, hydration tracking and restroom search functionalities. The SmartBag could operate without Alfred mobile app.

The figure below illustrates how data transfer will take place within the SmartBag between the wafer, bag, hub, and 11 Health Cloud. The sensors in the bag and the wafer will be able to transmit data to the hub via NFC protocol communication. The data from the hub will be transmitted to the cloud via LTE-M data transfer via secure MQTT protocol and then this data can be downloaded to web supported devices – such as an iPhone.



DEVICE INDICATIONS FOR USE **807.92(a)(5)**

Prescription Use Only

SmartBag is intended for use inside and out of hospitals for any patient with a diversionary urinary or fecal stoma. It works in conjunction with 11 Health's care management platform known as Alfred. The SmartBag system uses integrated sensors to continuously monitor bag filling and drainage, providing cumulative output data to the patient and clinical team. The system also monitors skin condition, the occurrence of leaks and visual condition of the stoma.

The SmartBag Sytem is for adult use only. (22 years and above)

OTC

SmartBag's intended use is to help ostomates acclimate to their lifestyle. It works in conjunction with 11 Health's care management platform known as Alfred, designed for patients and medical professionals. The SmartBag system (including the wafer and Hub), offers a continuous ostomy monitoring system, tracks the estimated volumetric filling of the bag and visual condition of the stoma using integrated sensor technology.

The SmartBag Sytem is for adult use only. (22 years and above)

COMPARISON OF TECHNICAL CHARACTERISTICS 807.92(a)(6)

Parameters	11 Health and Technologies, LLC	11 Health and Technologies, LLC
K Number	K140938	K181643
Regulatory Classification	Class I 21 CFR 876.5600	Class I 21 CFR 876.5900
Product Code	EXB	EXB
Secondary Product Code	EZQ, EZS	EZQ, EZS
Indications for Use	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.	SmartBag is intended for use inside and out of hospitals for any patient with a diversionary urinary or fecal stoma. It works in conjunction with 11 Health's care management platform known as Alfred. The SmartBag system uses integrated sensors to continuously monitor bag filling and drainage, providing cumulative output data to the patient and clinical team. The system also monitors skin condition, the occurrence of leaks and visual condition of the stoma. SmartBag's intended use is to help ostomates acclimate to their lifestyle. It works in conjunction with 11 Health's care management platform known as Alfred, designed for patients and medical professionals. The SmartBag system (including the wafer and Hub), offers a continuous ostomy monitoring system, tracks the estimated volumetric filling of the bag and visual condition of the stoma using integrated sensor technology. The SmartBag Sytem is for adult use only. (22 years and above)
Use Environment	Hospital and home use	Hospital and home use
Patient Population	Patients using ostomy bags	Patients using ostomy bags
Disposable	Single use	Single use - wafer and Smartbag Multiple Use - Hub
Device Design: Collection	Ostomy bag with portable sensor attachment	Ostomy bag with portable sensor attachment
Device Design: Fill Status	Visual and alert via temperature sensor detection which sends fill alert to a dedicated tablet computer	Visual and alert via sensor detection which sends fill alert to a dedicated tablet computer

Parameters	11 Health and Technologies, LLC	11 Health and Technologies, LLC
Pictorial comparison	 Ostomy bag and sensor consists of the bag and flexible resistor element, whose resistance changes depending on degree of flexure (bending). Once a desired "fill" level has been reached, an alert/alarm is sent via Bluetooth to a table to alert healthcare professionals that the ostomy bag requires immediate attention.	 Ostomy bag with integrated temperature sensors for notifying patients or medical professionals of any potential leaks around the peristomal skin as well as giving an estimate of the output volume within the bag.

NON-CLINICAL PERFORMANCE DATA **807.92(b)(1)**

PERFORMANCE TESTING

A series of in-house non-clinical bench experiments were conducted to prove the usability and functionality of the thermistors and capacitors. The experiments include but were not limited to:

- Simulated volumetric infusion test using materials with different viscosities to simulate ostomy excretion: to verify the volumetric sensor sheet's functionality of volumetric measurement

Test Report:

028_Testing Report 3_SmartBag Prototype Water and Apple Infusion Simulation Test

- Simulated volumetric infusion test on human volunteers in different body positions and movement: to verify the volumetric sensor sheet's functionality of volumetric measurement when user is in different body positions and doing physical activities 7 4

Test Report:

029_Testing Report 4_Double_Thermistor Sheet Volumetric Test in a Mimic Pouch Using Four Different Fluids Human

032_Testing Report 7_Volumetric Test on Human Volunteer Using Water and Apple Sauce

- Simulated volumetric test on human volunteers with different clothing options: to verify the volumetric sensor sheet's functionality of volumetric measurement when different pressure from clothing is applied to the ostomy bag as a wearable device 6

Test Report:

031_Testing Report 6_Clothing Test with Donut and Square Thermistor Sheets

- Simulated volumetric infusion test under high heat environment: to verify volumetric sensor sheet's functionality of volumetric measurement when external temperature is close to infusion temperature 5

Test Report:

030_Testing Report 5_Infusion Test in Environment Chamber

- Simulated leakage test using water at 37 °C to verify the wafer sensor sheet's functionality of leakage detection 2

Test Report:

027_Testing Report 2_Leakage Simulation Test Trial 3 Standing and Supine

- Simulated saturation durability test to verify the embedded water sensor sheet's durability 1

Test Report:

025_Testing Report 1a_SCAPA Wafer Prototype Saturation Test

026_Testing Report 1b_SCAPA Wafer Prototype 7 Days Saturation Test

CONCLUSION **807.92(b)(3)**

The volumetric sensor sheet is capable of:

- Detecting dynamic simulated infusions
- Detecting static volume of infused materials
- Recognizing different viscosities of the simulated infusions
- Measure volume of the simulated infusions when user is in standing or supine positions
- Measure volume of the simulated infusions when the environment temperature is close to infusion temperature, with the aid of capacitors

The wafer sensor sheet is capable to:

- Detect simulated leakage with the correct log interval
- Remain durable and functional after 7 days of saturation in 37 °C water bath

Consequently, the SmartBag prototype is proven to be functional for volumetric measurement and leakage detection from our simulated bench tests.

Substantial Equivalence Discussion

The primary intended use of an ostomy bag is a collection device. The SmartBag, does not alter an ostomy bag's function as a collection device but rather shares the same attributes with added features. The SmartBag offers a continuous ostomy monitoring system, tracking the estimated volumetric filling of the bag via integrated thermistor and capacitive sensors and potentially indicating the visual condition of the stoma with the optical sensor in the hub. Temperature distribution around the stoma, and anomalies in the temperature can suggest, inter alia, leakage occurrence, developing skin irritation and other phenomena in the peristomal region. Integrated sensors may indicate time of excretion, and data related to output, such as the phase (liquid, solid, semi-solid and gas). Data from the bag and wafer are transmitted securely by NFC to the hub which subsequently transmits data to the cloud via LTE. The data can be downloaded to a hand-held device like a cellphone or tablet for clinical purposes, if clinically indicated. The Smartbag raises no new issues of safety and effectiveness for its intended use but is a technological improvement of current approaches of simple visualization of ostomy fill and is substantially equivalent to both predicate device and reference device identified.