DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 29, 2017

Summit Medical Products, Inc
Mr. LeVoy Haight
CEO/President
504 West 8360 South
Sandy, Utah 84070

Re: K162165
Trade/Device Name: ambIT PCA*PIB, ambIT PIB, ambIT PIB*PCA, ambIT PIEB, and ambIT Programmable Intermittent Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: Class II
Product Code: MEA, FRN
Dated: July 27, 2016
Received: August 3, 2016

Dear Mr. Haight:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Tara A. Ryan -S

for
Lori Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*
K162165

Device Name
ambIT PCA*PIB, ambIT PIB, ambIT PIB*PCA, ambIT PIEB, and ambIT Programmable Intermittent Pump

Indications for Use *(Describe)*
The ambIT PCA*PIB Pump is used to infuse medicines and/or fluids into patients primarily for pain management.

The routes of administration are generally intravenous, epidural and/or regional.

The ambIT PCA*PIB Pump is not intended to supersede, augment, or replace any other medical device or drug indications for use or intended uses.

The ambIT PCA*PIB Pump is intended to be used in the home and in healthcare facilities.

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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SUMMIT MEDICAL PRODUCTS

August 29, 2017

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Trade Names: ambIT® PCA*PIB, ambIT® PIB, ambIT® PIB*PCA, ambIT® PIEB, and ambIT® Programmable Intermittent Pump
Common Name: PCA Infusion Pump or Infusion Pump
Classification Name: Infusion Pump
Regulation Number: 21 CFR 80.5725
Product Codes:
MEA, PCA Infusion Pump
FRN, Infusion Pump

Predicate Device
K002434—ambIT® PCA Pump

Reference Device
K130394 – CADD®-Solis Ambulatory Infusion Pump

Device Description
The new ambIT PCA*PIB is an electro-mechanically controlled, rotary-peristaltic, infusion pump that consists of two components: (1) the reusable pump driver; and (2) the sterile, single-use cassette (tubing set).

The ambIT PCA*PIB Pump has a microprocessor-controlled motor that turns the rollers in the cassette at a set frequency to provide the desired infusion rate/therapy. The ambIT PCA*PIB Pump is powered by two (2) standard 1.5-volt “AA” batteries, and cannot be powered by electrical mains. The batteries are replaceable but cannot be recharged inside the pump.

The controls consist of two buttons and an OFF/ON switch. One button toggles the pump between pause and infusing. The other button (BOLUS button) is used to request a bolus. An LCD display shows the pump status, alarms, and history. The pump monitors downstream occlusions, pump malfunctions, and other pump error conditions. The

materials of construction are all medical grade plastics. Specifically, the materials are ABS, polycarbonate, nylon, and glass-filled nylon.

The part of the pump that comes into indirect contact with the body is the cassette or tubing set. The medications flow through the tubing into a catheter and then into the body. The tubing set is classified to be used for less than 30 days.[1] The length of time the pump is used is based on the therapy requirements.

The ambIT PCA*PIB product has been validated and verified to meet healthcare providers', lay users', and patients' needs for pain management infusions. The pump meets all applicable national and international consensus standards.

Indications for Use

See Table 1 for a comparison of the Indications for Use between the new and predicate pumps.

Table 1: Indications for Use - The differences between the two indications for use are in *italics*.

ambIT PCA*PIB Pump	ambIT PCA Pump
The ambIT PCA*PIB Pump is used to infuse medicines and/or fluids into patients primarily for pain management. *The routes of administration* are generally intravenous, epidural and/or regional. *The ambIT PCA*PIB Pump is not intended to supersede, augment, or replace any other medical device or drug indications for use or intended uses.* *The ambIT PCA*PIB Pump is intended to be used in the home and in healthcare facilities.*	The ambIT PCA Pump is used to infuse medicines and/or fluids into patients primarily for pain management. *Modes of action* are generally intravenous, epidural and/or regional.

The differences in the indications for use are as follows:

The phrase "*modes of action*" has been changed to "*routes of administration*."

The last two sentences are added to the indication for use statement for completeness.

None of these changes or additions raise new questions of safety or efficacy in relation to the new ambIT PCA*PIB Pump.

[1] The classification is external communicating device, blood path-indirect, prolonged use.

Comparison to Predicate Pump

The new ambIT PCA*PIB Pump and the predicate ambIT PCA Pump utilize the same technology (microprocessor-controlled, rotary peristaltic pump), and the same cassettes (tubing set). They are built using the same materials and mechanical design, with the same dimensions and validated processes. They also have the same volumetric accuracy (±6%), operating conditions, storage conditions, LCD display, alarms/alerts, and power source. The user needs and specifications are the same for the predicate and new pump except for the addition of a programmable intermittent bolus (PIB) mode and more specificity and range in selecting the bolus volumes, lockout times, and the total volume to be infused.

The new ambIT PCA*PIB Pump and the predicate ambIT PCA Pump cannot be connected to a network or a computer.

The indications for use for the new ambIT PCA*PIB Pump and predicate ambIT PCA Pump are discussed above.

As was mentioned above, the new ambIT PCA*PIB Pump has additional user needs that led to software changes. The software changes allow for more specificity in choosing infusion volumes, bolus volumes, and lockout times when compared to the predicate pump. In addition, the PIB mode has been added as an option to replace the basal infusion rate with automated boluses (i.e., doses). It should be noted that throughout the remainder of this document, the term dose is defined as an automated bolus whose frequency is programmed by the healthcare provider.[2] The changes to the ambIT PCA*PIB Pump have been verified, validated, and shown to raise no new questions with regards to safety or efficacy. See Table 2 for details on the software differences.

Table 2. The differences between the predicate ambIT PCA Pump and new ambIT PCA*PIB Pump.

Parameter	ambIT PCA*PIB Pump	Predicate ambIT PCA Pump	Comments/Safety-related Discussion
Delivery Rate [of boluses and doses]	125-210 ml/hr	100 ml/hr	The delivery rate is not adjustable. It varies based on energy remaining in batteries.[3]

[2] To avoid confusing healthcare providers, the automated/Intermittent Bolus will be referred to as a dose and a patient-controlled analgesia (PCA) bolus will be called a bolus. The reason is that healthcare providers think of PCA when the term bolus is used and we are maintaining convention with regard to PCA boluses.

[3] The rate will be 210 ml/hr until a low-battery alarm occurs, and then the infusion-rate may drop as low as 125 ml/hr. The variance in delivery rate maximizes the battery life

Parameter	ambIT PCA*PIB Pump	Predicate ambIT PCA Pump	Comments/Safety-related Discussion
Bolus Volume	0-50 ml	0-20 ml	The initial or "loading" bolus is generally larger than 20 ml and can be as high as 50 ml. This allows for longer lockouts and the ability to "reload" the site later.
Lockout Time[4]	1 minute to 24 hours	5 minutes to 12 hours	The new pump allows the lockout to be set in 1 minute increments, while the predicate device allows only a limited number of specific values (00:05, 00:10, 00:20, 00:30, 00:45, 01:00, 01:30, 02:00, 04:00, 08:00, 12:00). The new pump also increases the range for the lockout time. Overall, the new pump allows for greater flexibility in setting lockout times to match the bolus volume.
Dose Volume	0-50 ml	NA	NA
Dose Interval[5]	1 minute to 24 hours	NA	This setting is required for a dose to occur at programmed intervals.
Total Infusion Volume	25 -1,000 mL	25-1,000 mL	The new pump allows infusion volumes to be set in 1 ml increments. The predicate device allows only a limited number of specific values (25, 50, 75, 100, 150, 200, 250, 300, 350, 400, 450, 500, 600,

[4] The lockout time is the time during which a bolus can be requested but won't be delivered. It starts after a bolus or dose has been delivered.
[5] The dose interval is the length of time that must pass before another dose will be able to be delivered.

Parameter	ambIT PCA*PIB Pump	Predicate ambIT PCA Pump	Comments/Safety-related Discussion
			700, 800, 900, 1000). The overall range is the same.
Ingress Protection	IP22	IPX1	The new pump has a higher ingress protection. The increase is in accordance with consensus home use standard, IEC 60601-1-11: 2010. The predicate ambIT PCA Pump currently has the same ingress protection, but when the 510(k) for the predicate ambIT PCA Pump was cleared, it was not tested to see if it met IP22.

The changes to the programming either provide a greater range (maximum bolus volume of 50 ml), allow for more specificity in programming the pump (in 1 ml increments or 1-minute increments), or allow for doses to replace the basal rate. The changes are based on feedback from healthcare providers. The programming changes were tested in a simulated environment with healthcare providers to see if the changes created any hazardous situations. The testing showed that no hazardous situations were created due to the software changes.

Comparison to Reference Pump

To address the software differences between the new and predicate pumps, the ambIT PCA*PIB Pump was compared to a FDA cleared reference product (CADD-Solis Pump – K130394). This comparison is given in Table 3 below. Comments following the table discuss how any differences between the two pumps do not call into question the safety and efficacy of the ambIT PCA*PIB Pump.

Table 3. The comparison between the reference CADD-Solis Pump and the new ambIT PCA*PIB Pump. Parameters in *italics* are the parameter names as found in the CADD-Solis specification literature (if different from the names used by Summit).

Parameter	ambIT PCA*PIB Pump	CADD-Solis Pump[6]	Comment
Routes of administration found in the indications for use	Intravenous	Intravenous	1
	Epidural	Epidural Space	
	Regional	NA	
	NA	Subcutaneous, intraperitoneal, in close proximity to nerves, intraoperative site (soft tissue, body cavity/surgical wound site)	
	N/A	Subarachnoid space	
Programming modes	PCA	PCA	NA
	PIB	PIB	
	PIB+PCA (P+P)	PIB+PCA	
Maximum Delivery Rate [of boluses or doses]	210 ml/hr	250 ml/hr[7]	2
Bolus Volume or *PCA Dose*	0-50 ml	0-50 ml	NA

[6] Smiths Medical *CADD-Solis Ambulatory Pain Management System with Programmed Intermittent Bolus (PIB)* Brochure.

[7] This maximum delivery rate is related to the standard volume tubing. For high volume tubing, the maximum rate is 500 ml/hr. It is not 'route of administration'-specific.

Parameter	ambIT PCA*PIB Pump	CADD-Solis Pump[6]	Comment
Lockout Time[8] or *PCA Dose Lockout*	1 minute to 24 hours in 1-minute increments	1 minute to 24 hours in the following increments: 1-minute increments for values between 1 and 20 minutes; 5-minute increments for values between 20 minutes and 24 hours	3
Dose Volume or *Intermittent Bolus*	0-50 ml	0-50 ml	NA
Dose Interval[9] or *Intermittent Bolus Interval*	1 minute to 24 hours in 1-minute increments	The amount of time from the start of one intermittent bolus to the start of the next intermittent bolus; 0 to 4 hours	4
Total Infusion Volume or *Reservoir Volume*	25 -1,000 mL; programmable in 1 mL increments, displayed in 0.1 mL increments	0 to 9999 ml; programmable in 1 mL increments, displayed in 0.1 ml increments	5
Infusion Accuracy	±6 %	±6 %	NA
Pump Type	Peristaltic	Peristaltic	NA

Comment 1 – The CADD-Solis Pump includes additional routes of administration in the indications for use than the ambIT PCA*PIB Pump.

Comment 2 – While the 100 ml/hr rate is acceptable in the predicated device, higher delivery rates for boluses and doses are added in an attempt to more closely mimic an actual injection.

[8] The lockout time is the time after a bolus has been delivered during which a bolus can be requested but won't be delivered.
[9] The dose interval is the minimum time from the start of one dose until the start of the next dose.

The CADD-Solis Pump has a maximum delivery rate of 250 ml/hr. The maximum delivery rate of the ambIT PCA*PIB Pump is 210 ml/hr. Thus, a previously cleared device has been shown to have as high or higher a delivery rate and the same maximum bolus and dose amounts. Thus, a delivery rate of 210 ml/hr via any of the proposed routes of administration does not raise any new questions of safety or efficacy.

Comment 3 – The ambIT PCA*PIB Pump has the same range as the CADD-Solis Pump for the Lockout Time/PCA Dose Lockout. The only difference is in the intervals available; the ambIT PCA*PIB Pump allows more specificity in selecting a lockout time after the first 20 minutes. This does not raise any new questions of safety or efficacy.

Comment 4 – The definitions of ambIT's 'dose interval range' and CADD's 'intermittent bolus interval' are the same – "The amount of time from the start of one intermittent bolus to the start of the next intermittent bolus"[10]; the difference between them is that the ambIT PCA*PIB Pump has a range of 1 minute to 24 hours, while the CADD-Solis Pump has a range of 0 to 4 hours. The availability of longer dose intervals allows the healthcare provider to provide a longer time for the drug to be cleared from the body. Thus, the difference between the ambIT PCA*PIB Pump's dose interval range and the CADD-Solis Pump's intermittent bolus interval does not raise any new questions of safety or efficacy.

Comment 5 – The total infusion volume intervals for the CADD-Solis Pump are the same as the ambIT PCA*PIB Pump - 1 ml intervals. Since the range of the ambIT PCA*PIB Pump's total infusion volume is the same as the predicate ambIT PCA Pump, having a narrower range than the CADD-Solis Pump does not raise any questions of safety or efficacy.

Non-Clinical Performance Data

Both the predicate ambIT PCA Pump and the new ambIT PCA*PIB Pump meet the same non-clinical performance data. The bench testing on the ambIT PCA*PIB Pump demonstrates that the new pump meets the same volumetric accuracy requirements (when delivering high, low, and median flow rates and bolus volumes), the same usability requirements, and the same downstream occlusion alarm specifications. The volumetric accuracy and occlusion alarm were tested and the results show that the new pump meets the same specifications as the predicate pumps. The usability test results showed that no new concerns related to safety were found when used by lay users or healthcare providers.

Both the predicate ambIT PCA Pump and the new ambIT PCA*PIB Pump meet the following standards: ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012; IEC 60601-1: 2012 Edition 3.1; IEC 60601-1-2:

[10] Smiths Medical *CADD-Solis Ambulatory Pain Management System with Programmed Intermittent Bolus (PIB)* Brochure.

2014 (Fourth Edition_2014-02); IEC 60601-1-6: 2010; IEC 60601-1-8: 2012 Edition 2.1; IEC 60601-1-11: 2010; IEC 60601-2-24; and IEC 62366-1: 2015 Edition 1.0. The software for all ambIT Pumps were designed following IEC 62304: 2006.

All bench/performance testing was completed using the cassettes (tubing sets). The cassettes also meet the standards listed above and sterilization standards. There were no changes to the fluid contacting components from the predicate device.

Following FDA guidance for infusion pumps, an assurance case was used to demonstrate that the new ambIT PCA*PIB Pump is adequately safe, adequately reliable and adequately designed for its intended use. The processes/techniques explained in ISO 14971 were used in identifying hazards and risks, ensuring that the risks were appropriately mitigated, and that the mitigation was effective. The assurance case shows that the four infusion pump system hazards[11] identified in the FDA infusion pump guidance were considered and mitigated. All eight sources of hazardous situations[12] specified in the FDA infusion pump guidance were evaluated by the risk management team. The risk management team determined what hazardous situations from each source could lead to the four infusion pump hazards. The risk management team consisted of clinical, engineering, marketing, and operational personnel.

Additional sources of information used to identify hazards and associated hazardous situations included the following: (1) MDR/Vigilance reports for predicate devices; (2) recall and MDR/Vigilance reports for other infusion pumps; (3) feedback from users via sales representatives and the customer support hotline; (4) non-conforming product reports for predicate products; (5) formative and summative human factors testing; (6) published and non-published articles; (7) specific consensus standards; (8) FDA guidance documents, and (9) nurses, healthcare providers, engineers (software, hardware, and mechanical), and RA/QA personnel.

Clinical Performance Data

Clinical Performance Data was not relied on to show substantial equivalence.

Summary

Based on the comparison of the new ambIT PCA*PIB Pump and the predicate ambIT PCA Pump, the new ambIT PCA*PIB Pump is substantially equivalent to the predicate ambIT PCA Pump.

[11] The four infusion pump system hazards are (1) infusion delivery error, (2) incorrect therapy, (3) biological/chemical contamination, and (4) traumatic injury.

[12] The eight sources of hazardous situations are (1) operational, (2) environmental, (3) electrical, (4) hardware, (5) software, (6) mechanical, (7) biological and chemical, and (8) use.