August 2, 2018

B. Braun Medical Inc.
Tracy Maddock
Sr. Regulatory Affairs Specialist
901 Marcon Blvd
Allentown, Pennsylvania 18109

Re: K173531
Trade/Device Name: Lockbox for the Perfusor Space PCA Infusion Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: MRZ
Dated: June 22, 2018
Received: June 25, 2018

Dear Tracy Maddock:

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,

Alan M. Stevens -S

for Tina Kiang, Ph.D.
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)*
K173531

Device Name
Lockbox for the Perfusor® Space PCA Infusion Pump

Indications for Use *(Describe)*
The Lockbox is intended to hold a Perfusor® Space PCA Infusion Pump and provide reasonably secure access to the medication syringe contained within.

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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K173531 510(k) Summary

Submitter:	B. Braun Medical Inc. 901 Marcon Boulevard Allentown, PA 18109-9341 610-266-0500 Establishment Registration: 2523676
Application Correspondent:	Tracy Maddock, RAC Sr. Regulatory Affairs Specialist Phone: (610) 596-2545 Fax: (610) 266-4962 E-mail: tracy.maddock@bbraun.com
Preparation Date:	August 2, 2018
Trade Name:	Lockbox for the Perfusor® Space PCA Infusion Pump
Common or Usual Name:	Accessories, Pump, Infusion
Regulation Name:	Infusion pump
Regulation Number:	21 CFR 880.5725
Product Code:	MRZ
Device Class:	Class II
Primary Predicate Device:	K091181 – Lockbox for Use with Medfusion 3000 Series Pumps

Indications For Use:
The Lockbox is intended to hold a Perfusor® Space PCA Infusion Pump and provide reasonably secure access to the medication syringe contained within.

Device Description:
The Lockbox is a lockable, clear plastic enclosure designed to house a B. Braun Perfusor® Space PCA Syringe Infusion Pump and secure it onto a vertical IV pole. The Lockbox consists of a two part polycarbonate enclosure consisting of a front housing and a rear housing. The rear housing has two guide rails which position the pump in the Lockbox. The left guiderail contains a detent which serves to hold the pump in place.

The rear housing contains three openings, one to allow for the release of the pump from the detent in the left guide rail, one that allows for connection of the power and PCA cables, and slotted openings allowing for alarms to be heard while the infusion pump is in the Lockbox. A front housing is connected to the rear case by means of a full length hinge designed into the polycarbonate material. When closed, the Lockbox is secured by a keyed lock preventing access to the syringe contents contained within the infusion pump. A cut-out in the front housing provides a clinician direct access to the user interface keys and display screen.

An aluminum pole clamp, designed to operate with a vertical IV pole is attached to the Lockbox. Once attached to the IV pole, the pole clamp can be locked to prevent the Lockbox from being removed from the pole.

Device Comparison of Technology

The proposed device has the same intended use (to provide reasonably secure access to the medication syringe contained within) and the same principle of operation as the predicate device. The proposed device design is the same as the predicate device in that both Lockboxes are constructed of a durable, clear plastic material that encloses the pump securing the syringe, tubing connection, and syringe mounting and driving mechanisms. Both Lockboxes provide access to the pump controls and power cords through window's cut out of the plastic. Locking mechanisms on the pump door restrict access to the syringe for both devices.

A table summarizing the comparison between the Lockbox for the Perfusor® Space PCA Infusion Pump and the predicate device is provided below.

Attribute	**Subject Device** **Lockbox for Perfusor® Space PCA** **K173531**	**Predicate Device** **Lockbox for Medfusion™ 3000 Series Pumps** **K091181**	**Comparison**
Intended Use	The Lockbox is intended to provide reasonably secure access to the medication syringe contained within.	The Lockbox is intended to provide reasonably secure access to the medication syringe contained within.	Same
Indications for Use	The Lockbox is intended to hold a Perfusor® Space PCA Infusion Pump and provide reasonably secure access to the medication syringe contained within.	The Lockbox is intended to hold a Medfusion™ 3000 Series Pump and provide reasonably secure access to the medication syringe contained within.	Different

Attribute	Subject Device Lockbox for Perfusor® Space PCA K173531	Predicate Device Lockbox for Medfusion™ 3000 Series Pumps K091181	Comparison
Material	Thermoformed clear plastic	Thermoformed clear plastic	Same
Enclosure	Encloses pump securing the syringe, tubing connection and syringe-mounting and driving mechanisms.	Encloses pump securing the syringe, tubing connection and syringe-mounting and driving mechanisms	Same
Enclosure Security	Keyed lock with full length hinge pin	Keyed lock with dual hinge points	Different
Pump control access	Open window allows access to pump display and keypad	Open window allows access to the pump display and keypad	Same
Power cord access	Open access for power cord	Open access for power cord	Same
Mounting	IV pole with locking mechanism	IV pole, Horizontal rectangular rail, Shelf	Different
Transporting	Carry handle	Carry handle	Same

Substantial Equivalence Discussion
The differences between predicate and proposed devices include:

- The Lockbox for the Perfusor® Space PCA Infusion Pump includes a locking mechanism on the pole clamp to secure the Lockbox to the IV pole during use. The pole clamp locking mechanism is intended to prevent removal of the lockbox from the IV Pole.

- The indications for use differ specifically on the infusion pump specified for use with the Lockbox. The proposed device, the B. Braun Lockbox, was designed and intended for use with the B. Braun Perfusor® Space PCA Infusion Pump whereas the predicate device, the Medfusion Lockbox, was designed and intended for use with the Medfusion™3000 Series Pumps.

- The proposed device utilizes a full length hinge pin whereas the predicate device utilizes a dual hinge point design. The full length hinge pin provides support along the entire hinge keeping the door and the frame in alignment.

- Mounting of the proposed B. Braun Lockbox is on a vertical IV pole. Mounting of the predicate Medfusion Lockbox is also via a vertical IV pole but can also accommodate a horizontal rectangular rail or shelf.

The differences, between subject device and predicate device, do not raise different questions of safety and effectiveness.

Performance Testing Summary:
Non-clinical tests were conducted to verify that the proposed device met all design specifications and is substantially equivalent (SE) to the Lockbox for Medfusion™ 3000 Series Pumps. The proposed Lockbox was subjected to the following functional and performance testing to demonstrate that it performs as intended:

- Visual inspection
- Drop test
- Visual and audible pump indicator testing
- Drop/tamper resistance testing
- Pole clamp testing – including lock, latch and knob functional and reliability testing
- Door cycle testing
- Chemical resistance testing
- Cleaning and disinfection validation
- Simulated distribution/shipping testing in accordance with ASTM D4169-16 - Standard Practice for Performance Testing of Shipping Containers and Systems

A risk analysis was conducted in accordance with ISO 14971: 2007 – Medical devices — Application of risk management to medical devices.

No clinical testing was performed as this device does not require clinical studies to demonstrate substantial equivalence with the predicate device.

In all testing, the pre-determined acceptance criteria were met. Results of the testing demonstrate that the proposed device meets its intended use.

Substantially Equivalence Conclusion:
The intended use and technological characteristics of the subject device do not raise different questions of safety and effectiveness as compared to the predicate device. The performance of the device is supported by non-clinical testing and risk management activities. The Lockbox for the Perfusor® Space PCA Infusion Pump is substantially equivalent to the Lockbox for Medfusion™ 3000 Series Pumps, cleared under K091181.