DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 25, 2017

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

Re: K151423
Trade/Device Name: APEX Compounding System Transfer Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: LHI, NEP
Dated: January 13, 2016
Received: January 14, 2016

Dear Ms. Tracy Maddock:

This letter corrects our substantially equivalent letter of February 19, 2016.

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 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 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,

Michael J. Ryan -S

for Lori A. 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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K151423

Device Name
APEX Compounding System Transfer Set

Indications for Use *(Describe)*
The APEX Transfer Set is intended to be used with the APEX Compounding System. The administration sets are to be used in a sterile compounding environment within a pharmacy to provide a fluid path for the compounding of ingredients from multiple source containers into a final solution.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510(k) Summary K151423

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DATE: February 18, 2016

DEVICE NAME: APEX Compounding System Transfer Set

COMMON OR USUAL NAME: IV Fluid Transfer Set

DEVICE CLASSIFICATION: Class II per 21 CFR 880.5440 Intravascular administration set
Product Code: LHI, NEP
Classification Panel: General Hospital

PREDICATE DEVICE: Exacta-Mix 2400 Compounding System Administration set, Baxa Corporation K002705, Class II, LHI, 880.5440.

DESCRIPTION:

The Apex Compounding System Transfer Set consists of a valved manifold with micro, macro and flex source lines. The proximal end of the source line consists of a luer lock connector which allows for connection to a transfer spike or connector depending upon the source container being used. The outlet tubing connects each valve, through the manifold body and consists of two sections of pump tubing just before ending at a final container connector, a luer adapter, to connect to a final container bag for eventual patient administration. There are 26 source lines on the manifold which correspond to the device's ability to support 26 source containers. Each individual line is labeled with a unique numeric identifier and barcode for traceability and scanning.

INDICATIONS FOR USE:

The APEX Transfer Set is intended to be used with the APEX Compounding System. The administration sets are to be used in a sterile compounding environment within a pharmacy to provide a fluid path for the compounding of ingredients from multiple source containers into a final solution.

SUBSTANTIAL EQUIVALENCE:

The APEX Compounding System Transfer Set is substantially equivalent to the Baxa Exacta-Mix 2400 Compounding System Administration Set (K002705).

Comparison of Technological Characteristics with the Predicate Device

The subject device has the same indications for use (to provide a fluid path for the compounding of ingredients from multiple source containers into a final solution) and the same principle of operation as the predicate device. The subject Transfer Set is similar in design with respect to components and materials of construction. Both devices are provided as sterile, nonpyrogenic, individually packaged devices to be used with their respective compounding devices.

A table summarizing the comparison between the APEX Transfer Set and the predicate device is provided below.

SUBJECT DEVICE: **APEX COMPOUNDING SYSTEM TRANSFER SET**	**PREDICATE DEVICE:** **EXACTA-MIX 2400 COMPOUNDING SYSTEM ADMINISTRATION SET (K002705)**
INDICATIONS FOR USE	
The APEX Transfer Set is intended to be used with the APEX Compounding System. The administration sets are to be used in a sterile compounding environment within a pharmacy to provide a fluid path for the compounding of ingredients from multiple source containers into a final solution.	The Exacta-Mix 2400 compounding system administration sets, manufactured by Baxa Corporation, are ancillary devices used in conjunction with the Exacta-Mix 2400 compound device. The administration sets are used in the pharmacy to provide the fluid path for multiple source ingredients into one final solution.
DESCRIPTION	
Transfer set is a sterile, non-pyrogenic, disposable, individually packaged device designed to work in conjunction with the APEX compounding system to quickly and accurately compound multi-ingredient sterile solutions by withdrawing requested amounts of source ingredients from their containers in a user specified sequence into a final container.	Transfer set is a sterile, non-pyrogenic, disposable, individually packaged device designed to work in conjunction with the Baxa EM-2400 compounding system to quickly and accurately compound multi-ingredient sterile solutions by withdrawing requested amounts of source ingredients from their containers in a user specified sequence into a final container.

SUBJECT DEVICE: **APEX COMPOUNDING SYSTEM TRANSFER SET**	**PREDICATE DEVICE:** **EXACTA-MIX 2400 COMPOUNDING SYSTEM ADMINISTRATION SET (K002705)**
TECHNOLOGY	
✓ Twenty-six (26) inlet sources ✓ Micro or macro volume fluid transfer ✓ 25 L max use, micro side / 300 L max use, macro side ✓ Set requires attachment of transfer spikes or connector	✓ Twenty- four (24) inlet sources ✓ Micro or macro volume fluid transfer ✓ 150 L max use ✓ Set requires attachment of inlet tubing sets
COMPONENTS AND MATERIALS	
Manifold Body: Polycarbonate	**Valve Set Body:** Polycarbonate
Valve: TPV	**Valve Core:** Santoprene
Pump Tube: Silicone	**Outlet Pump Tube:** Silicone
Final Container Adapter: ABS	**Large-Bore Connector:** ABS
Final Container Adapter Cap: ABS	**Connector Cap:** HDPE
Inlet Male Luer Lock Connector: ABS, Acrylic	**Inlet Connector:** ABS
Connector Cap: HDPE	**Cap:** Polycarbonate
Source Line Tubing: PVC	**Inlet tubing:** PVC
	Outlet Connector: Thermoplastic Elastomer
TESTING	
• Visual inspection • Leakage • Static Load • Joint tensile strength • Valve torque • Vacuum • Occlusion • Luer gauging • Barcode scan • Magnetic flux density • Associate device (Delivery accuracy, Specific gravity interchange, Leakage, Fit) • Life cycle testing - Spallation and Particulate contamination	Accuracy Fluid/air Leakage Precipitant
STERILIZATION	
Method: Ethylene oxide (EO) **Sterility Assurance Level (SAL):** 10^{-6}	**Method:** Gamma **Sterility Assurance Level (SAL):** 10^{-6}

The differences between the predicate device and the subject device include:

- The subject device has pre-attached source lines with male luer lock connectors and bar-coded flags indicating the line number. The predicate device consists of a valve set and separate inlet lines to be added by the user. Additionally, the user must attach barcode labels to the inlet lines.

- The subject device contains twenty-six (26) source lines giving the user the ability to compound solutions using 26 source containers. The predicate device has the potential for twenty-four (24) source lines.
- The subject device and the predicate device allow the compounding of both micro and macro volumes. The predicate device has one fluid channel through the valve set. The subject device has two (2) channels, a micro channel and a macro channel.
- The sterilization method for the subject device is ethylene oxide whereas the sterilization method for the predicate device is gamma irradiation.

The differences, between subject device and predicate device, do not raise any new issues of safety and effectiveness.

Performance Testing

The proposed APEX Transfer sets were subjected to functional and performance testing to demonstrate that the sets perform as intended.

The following testing was performed on the subject device to the performance criteria listed or included in the referenced standard.

- **Visual inspection** – free of cracks, damage, kinked tubes, holes, disconnected components, valves seated within 5% of alignment
- **Leakage** – no bubbles observed at joints with 10 psi air pressure (positive pressure), vacuum pressure shall not fall in 30s while applying 28 in Hg (negative pressure)
- **Joint strength**
  - Static load tensile force (ISO 8536-4)
  - Peak pull force – joints shall be $\geq$ 5 lbf pulled to failure at 14 in/min (7 lbf for macro pump tube joints)
- **Valve torque** – micro valve torque shall not exceed 14.2 oz in, macro valve torque shall not exceed 42.5 oz in
- **Vacuum test** – vacuum pressure shall not fall in 30s while applying 28 in Hg
- **Occlusion test** – bubbles shall be observed from end after applying 0.5 psi air pressure while immersed
- **Luer gauging** (ISO 594-2)
- **Barcode Scan** – scan shall match human readable number
- **Magnetic flux density** – shall be $\geq$ 40 Gauss at a distance of 0.28”
- **Life cycle testing** (Spallation and Particulate contamination**)** – USP 788 after simulated use
- **Biocompatibility** (ISO 10993-1)
  - Cytotoxicity (MEM Elution, ISO 10993-5)
  - Delayed-type hypersensitivity (Guinea Pig Maximization, ISO 10993-10)
  - Intracutaneous Reactivity (ISO 10993-10)
  - Acute Systemic Toxicity (ISO 10993-11)
  - Hemocompatibility (Hemolysis, ASTM F756, ISO 10993-4)

- Material-Mediated Pyrogenicity (Rabbit Pyrogen, USP <151>, ISO 10993-11)

- **Associate device** (APEX Compounding System)
  - Delivery accuracy –

    Dextrose 70% at 20-25°C shall be ± 10% at 0.2 mL, ± 3% above 1 mL.

    Dextrose 70% at 15-30°C shall be ± 10% at 0.2 mL, ± 6% above 1 mL.

    Other solutions at 15-30°C shall be ± 10% at 0.2 mL, ± 3% above 1 mL.
  - Fit –set shall be able to be attached and removed with audible and tactile feedback and without damage to components
- **Associate device** (B. Braun Spikes and Fluid Connector, B. Braun Final Containers)
  - Leakage –
    - Source lines - no bubbles observed at connections after applying air pressure while immersed, vacuum pressure shall not fall in 30s while applying 28 in Hg
    - Final container connector – no leakage when subjected to water pressure source of 20 psi

The following comparative testing was performed on the subject and predicate device:

- Specific Gravity Interchange – mean concentration of unintended ingredient during compounding for the subject device shall be $\leq$ mean concentration of unintended ingredient during compounding for the predicate device

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

CONCLUSION:

Results of functional and performance testing conducted on the subject device demonstrate that the APEX Transfer Set is substantially equivalent to the predicate device.