Hospira, Inc.
Dr. Rebecca Andersen
Global Regulatory Affairs Devices Manager
Department-0389 Building H2
275 North Field Dr.
Lake Forest, Illinois 60045

March 11, 2022

Re: K080579
Trade/Device Name: Effectiv™ Cap
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: QBP

Dear Dr. Rebecca Andersen:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your original substantial equivalence (SE) determination letter dated September 11, 2008 and the correction letter dated March 12, 2019. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under regulation 880.5440.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Payal Patel, OHT3: Office of GastroRenal, Ob-Gyn, General Hospital and Urology Devices, 240-402-6029, Payal.Patel@fda.hhs.gov.

Sincerely,

Payal Patel
Assistant Director for General Hospital Devices
DHT3C: Division of Drug Delivery and General Hospital Devices and Human Factors
OHT3: Office of GastroRenal, Ob-Gyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

FDA U.S. FOOD & DRUG ADMINISTRATION

March 12, 2019

Hospira, Inc.
Rebecca Andersen
Global Regulatory Affairs Devices Manager
275 North Field Dr.
Lake Forest, Illinois 60045

Re: K080579
Trade/Device Name: Effectiv™ Cap
Regulatory Class: Unclassified
Product Code: QBP
Dated: February 20, 2008
Received; March 3, 2008

Dear Rebecca Andersen:

This letter corrects our substantially equivalent letter of September 11, 2018.

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 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,

FDA
Geeta K.
Pamidimukkala -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

Section 5: Indications for Use

510(k) Number (unknown at this time) K080579

Device Name: **Effectiv™ Cap**

Pad, Alcohol, Device Disinfectant

Indications for Use:

The Effectiv™ Cap is a device containing 70% Isopropyl alcohol. When left in place for 5 to 10 minutes the cap decontaminates the injection port; thereafter the cap provides a physical barrier during intended use.

Prescription Use __X__ **AND/OR** **Over-The-Counter Use**_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080579

K080579
1 of 2

Effectiv™ Cap 510(k)
9/9/08

SEP 1 1 2008

Section 6: 510(k) SUMMARY Effectiv™ Cap

1. **Submitted by:**

Hospira, Inc.
D-389, Bldg. H2
275 N. Field Drive
Lake Forest, IL 60045

Phone: (224) 212-5270
Fax: (224) 212-5401

Contact: Rebecca Andersen

2. **Date Prepared:** February 28, 2008

3. **Name/Classification of Device:** **Pad, Alcohol, Device Disinfectant**
Unclassified
LKB

4. **Trade Name of Proposed Device:** Effectiv™ Cap

5. **Predicate Devices:**

Device Name	510(k) Number
Alcohol Swab – Aplicare, Inc.	K833182
Lifeshiled Gravitech Flow Set (with cap) - Hospira	K063239

6. **Proposed Device Description:**
The Effectiv™ Cap is a cap that holds a sponge soaked with 70% Isopropyl Alcohol (IPA). The cap is provided sterile, Non-DEHP, latex free, single use, and is disposable. The Effectiv™ Cap is used with standard needleless ports. The Effeciv™ Cap is packaged individually, and sold in cartons.

7. **Statement of Intended Use:**
The Effectiv™ Cap is a device containing 70% Isopropyl alcohol. When left in place for 5 to 10 minutes the cap decontaminates the injection port; thereafter the cap provides a physical barrier during intended use.

8. **Summary of Technological Characteristics of New Device Compared to Predicate Devices**

The subject and predicate devices are similar in principle of operation, intended use, and labeling.

K080579
2 of 2

The Alcohol Swab is a non woven pad saturated with 70% Isopropyl alcohol for surface cleaning and disinfecting. The Efectiv™ Cap has a sponge saturated with 70% Isopropyl Alcohol. However, because of its special configuration, a sponge inside the Effectiv™ Cap, its use is restricted to decontamination of injection ports, usually on an IV set, prior to injection.

The claim for substantial equivalence is supported by the information and performance test data provided in the 510(k) submission.