DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 1, 2016

Concert Medical, LLC
% Ms. Pamela Papineau, RAC
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
Ayer, Massachusetts 01432

Re: K153599
Trade/Device Name: Concert Medical Hands-Free Syringe (HFS)
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: Class II
Product Code: FRN
Dated: August 8, 2016
Received: August 9, 2016

Dear Ms. Papineau:

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 yours,

Christopher J. Ronk -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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 below.

510(k) Number *(if known)*
K153599

Device Name
Concert Medical Hands-Free Syringe (HFS)

Indications for Use *(Describe)*
The Concert Medical Hands-Free Syringe (HFS) is indicated for general fluid irrigation/infiltration.

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.

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

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Appendix C – 510(k) Summary (revised)

General Information

Date Prepared:	August 26, 2016
Owner's Name:	Concert Medical, LLC
Address:	77 Accord Park Drive Norwell, MA 02061
Owner Contact Person:	Timothy S. Powers, V.P. Operations/Regulatory
Telephone Number:	781-261-7407
Regulatory Contact Person:	Pamela Papineau, RAC
Telephone Number:	978-772-3552
Subject Device Name:	Concert Medical Hands-Free Syringe (HFS)
Trade Name:	Concert Medical Hands-Free Syringe (HFS)
Common/Usual Name:	Infusion Pump
Product Code:	FRN
Classification Name:	Infusion Pump 21 CFR 880.5725; Class II
Predicate Device:	Psi-Tec Syringe Infusion Pump and Accessories
Trade Name:	Psi-Tec Syringe Infusion Pump and Accessories
Common/Usual Name:	Infusion Pump
Product Code:	FRN
Classification Name:	Infusion Pump 21 CFR 880.5725; Class II
Premarket Notification:	K980738; Byron Medical Psi-Tec Syringe Infusion Pump and Accessories SE date June 16, 1998
Primary Reference Device:	KleinTouch Pump
Trade Name:	KleinTouch Pump
Common/Usual Name:	Infusion Pump
Product Code:	FRN
Classification Name:	Infusion Pump 21 CFR 880.5725; Class II
Premarket Notification:	K123822; HK Surgical KleinTouch Pump SE date September 27, 2013

Indications for Use

The Concert Medical Hands-Free Syringe is indicated for general fluid irrigation/infiltration.

Device Description

The Concert Medical Hands-Free Syringe (HFS) is an infiltration pump used to infuse fluids (such as regional anesthetics) into the body. The HFS consists of a sterile, single-use plastic syringe (20 mL capacity) fitted with a custom plunger, a reusable motor housing, and a reusable foot pedal. The user fills the syringe with the fluid of choice, then locks the filled syringe into the motor housing, where the specially designed syringe plunger rack mates with the custom plunger housing gear. The male luer fitting of a sterile, single-use needle set (not supplied by Concert Medical) is attached to the standard female luer fitting on the HFS syringe. The foot pedal connector is plugged into the receptacle on the motor housing, then the foot pedal is placed in a convenient location on the floor. The motor housing contains non-replaceable AAA batteries, which power a small DC motor which in turn controls the movement of the syringe plunger. The foot pedal consists of a color-coded rubber bar; when the user applies light foot pressure to the appropriate half of the foot pedal (green = infuse; yellow = aspirate), the motor activates the plunger movement mechanism to move the plunger forward (infuse) or backward (aspirate). The motor control is designed to deliver fluid at a maximum flow rate of 0.5 mL/sec. The motor is designed with an overpressure safety feature, which causes the plunger movement to stop if the pressure in the syringe exceeds 15 psi regardless of whether the "infuse" portion of the foot pedal is depressed. The motor housing has three LED indicator lights for real-time display of the syringe plunger action: a green light illuminates when the syringe is infusing, a yellow light illuminates when the syringe is aspirating, and a red light illuminates if the plunger movement has stopped because the 15 psi pressure limit has been reached. The foot pedal control provides the user with two-handed control of the needle placement without the need for a second person to manipulate the syringe plunger for infusion or aspiration.

Substantial Equivalence

The Concert Medical HFS is substantially equivalent to the Byron Medical Psi-Tec Syringe Infusion Pump and Accessories, which was cleared in K980738. The Psi-Tec Syringe Infusion Pump consists of a pneumatic-driven syringe pump used to irrigate or infuse fluids contained in a reservoir consisting of a sterile, disposable 10 mL piston syringe with a standard luer connector that is attached to a sterile, disposable tubing set for delivery of the fluid contained in the syringe. As for the Concert Medical Hands-Free Syringe, infusion/aspiration using the Psi-Tec Syringe Infusion Pump is controlled via a foot pedal. Flow rates for the Psi-Tec Syringe Infusion Pump range from 0 – 600 mL/min. The maximum infusion pressure of the Concert Medical Hands-Free Syringe (15 psi) is equivalent to that of the Psi-Tec Syringe Infusion Pump (14.8 psi). The Macosta Medical B-Smart Nerve Block Injection Pressure Manometer (K031128), which is used in conjunction with a standard infiltration anesthesia needle set to limit infusion pressure to a maximum of 15 psi, is cited as a reference device for the maximum 15 psi infusion pressure of the Concert Medical HFS.

The HK Surgical KleinTouch Pump, which was cleared in K123822, is cited as a reference device for the Concert Medical Hands-Free Syringe. The KleinTouch Pump is indicated for use as an infiltration pump used to cause a flow of fluid from an IV bag into a patient in a manner controlled manually by a health care professional. The KleinTouch Pump consists of a powered (battery or AC), reusable peristaltic roller pump that achieves fluid movement via force exerted

by three rollers on the plastic tubing connecting the fluid reservoir (IV bag) to the infusion needle. The KleinTouch Pump is used with the sterile, single-use KT20 KleinTouch Tubing. The user activates the KleinTouch Pump via a foot pedal. The KleinTouch Pump can be used with 12g – 20g needles; infusion flow rates of 50 – 1000 mL/min are available depending on the selected needle gauge.

This 510(k) includes a second reference device, the Macosta Medical B-Smart Nerve Block Injection Pressure Manometer (K031128); the B-Smart device is used in conjunction with a standard infiltration anesthesia needle set to limit infusion pressure to a maximum of 15 psi.

Non-Clinical Performance Testing

Performance data demonstrated that the Concert Medical HFS has met pre-determined acceptance criteria and is substantially equivalent to the predicate device. The risks associated with the new device were found acceptable when evaluated in accordance with ISO 14971:2007. Performance testing included in this 510(k) consists of foot pedal / syringe plunger control functionality, overpressure cutoff functionality, maximum flow rate testing, flow rate measurement, limited reuse functionality testing of the motor control unit and foot pedal, and electrical safety/EMC testing. This submission also includes an Infusion Pump Safety Case and the results of a Human Factors study.

Conclusion

The Concert Medical Hands-Free Syringe (HFS) meets all pre-determined acceptance testing criteria performed to confirm substantial equivalence to the predicate device.