



Food and Drug Administration
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January 14, 2016

Liebel-Flarsheim Company, LLC
Craig Buehler
Sr. Regulatory Affairs Specialist
2111 East Galbraith Rd
Cincinnati, Ohio 45237

Re: K152361

Trade/Device Name: OptiOne Single-Head Contrast Delivery System
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector And Syringe
Regulatory Class: Class II
Product Code: IZQ
Dated: December 14, 2015
Received: December 15, 2015

Dear Craig Buehler:

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,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K152361

Device Name
OptiOne Single-Head Contrast Delivery System

Indications for Use (Describe)

The OptiOne Single-Head Contrast Delivery System is a contrast delivery system and is designed to inject radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e. "CT") equipment.

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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Section 5: 510(k) Summary

I. SUBMITTER

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 Date Prepared: 19 August 2015

II. DEVICE

Name of Device: OptiOne Single-Head Contrast Delivery System
 Common or Usual Name: Power Injector
 Classification Name: Injector, Contrast Medium, Automatic (21 CFR 870.1650)
 Regulatory Class: II
 Product Code: IZQ

Model Number	Description
847002	Injector, OptiOne Base System
S8472	OptiOne Single-Head Contrast Delivery System with Pedestal
S8473	OptiOne Single-Head Contrast Delivery System with Ceiling Suspension

III. PREDICATE DEVICE

OptiVantage DH Injector System with Enhanced Communication (K063503)

IV. DEVICE DESCRIPTION:

The OptiOne Single-Head Contrast Delivery System (OptiOne) is intended to inject radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used in conjunction with computed tomography equipment. Each injection is accomplished with a motor-driven syringe mechanism with microprocessor control of the flow rate, volume, pressure and timing. The OptiOne consists of the following key components: a Powerhead, a Console, and a Power Supply. The Power



Supply delivers power to the Powerhead and Console. The Console provides remote control and programmability of the injection through a touch screen display system. The Powerhead contains the components to perform the actual injection such as motor, motor control circuits, ball screw and syringe push ram.

The OptiOne is intended for use by doctors, radiology technologists and other licensed medical practitioners in a healthcare facility or hospital with computed tomography equipment.

The OptiOne incorporates the same materials as its predicate device and will not contact the patient under normal operation conditions.

V. INDICATIONS FOR USE

The OptiOne Single-Head Contrast Delivery System is a contrast delivery system and is designed to inject radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e. "CT") equipment.

The OptiOne and the OptiVantage predicate device both have the same indication for use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The OptiOne Single-Head Contrast Delivery System (OptiOne) was developed using the predicate device, OptiVantage DH Injector System with Enhanced Communication (OptiVantage), as the basis for the injector design. Many of the same components and accessories found in and used with the OptiVantage are also found and used with the OptiOne. The main difference between the OptiOne and its predicate is the OptiVantage is a dual head injector and the OptiOne is a single head injector.

The OptiOne has the same technological characteristics as the predicate OptiVantage. These similarities and the differences reducing the powerhead from the predicate device's dual head to a single head are described in the table beginning on the next page.



Feature	OptiOne Single-Head Contrast Delivery System	OptiVantage DH Injector System with Enhanced Communication (K063503)
Indication for Use	is a contrast delivery system and is designed to inject radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e. "CT") equipment.	Same
Number of Phases	4 phases per protocol maximum	6 phases per protocol maximum
Protocol Storage	40 protocols	Same
Syringe Sizes	125 mL, 100 mL, 75 mL, 50 mL pre-filled 200 mL empty	Same
Single or Dual Syringe Modality	Single Syringe Capability	Single and Dual Syringe Capability
Syringe Drive System	Electromechanical	Same
Syringe Heater	98° ± 6° F (37° ± 3° C) nominal. Maintains the temperature of pre-heated contrast (not intended to heat cold/room temperature contrast).	Same
Auto Syringe Fill Rate	7.0 mL/s Tolerance: +/-5%	Same
Manual Fill Rate	2.0 – 15 mL/s Tolerance: +/- 1 mL/s	Same
Flow Rate	0.1 – 10 mL/s adjustable in increments of 0.1 mL/s Tolerance: +/-0.05 mL/s for Flow Rates less than 1 mL/s +/-5 % for Flow Rates 1 mL/s to 10 mL/s	Same
Peak Pressure Limit	Pounds per Square Inch (psi): 50 – 325 adjustable in 5 psi increments kPa: 345 – 2240 adjustable in 34 kPa increments	Same



Feature	OptiOne Single-Head Contrast Delivery System	OptiVantage DH Injector System with Enhanced Communication (K063503)
Remote Start	Use of the remote hand switch allows the operator to perform injections from outside the area of direct radiation.	Same
Scan Delay	0 – 600 seconds adjustable in increments of 1 second	Same
Phase Delay	0 – 600 seconds adjustable in increments of 1 second or permanent pause	Same
Inject Delay	0 – 600 seconds adjustable in increments of 1 second	Same
OptiBolus	Yes - The OptiBolus feature is used to deliver an exponentially decaying flow rate injection that optimizes the contrast usage and provides an extended period of uniform enhancement of the area of interest.	Same
Universal Console	12.25 W x 2.5 H x 8.5 D inches (311 W x 64 H x 216 D mm) 5.8 lbs (2.6 kg)	Same
Powerhead	7 W x 6 H x 12.25 D inches (178 W x 152 H x 311 D mm) 10.4 lbs (4.7 kg)	12.5 W x 6 H x 8 D inches (318 W x 152 H x 203 D mm) 14.5 lbs (6.57 kg)
Power Supply	10 W x 4 H x 9 D inches (267 W x 102 H x 228 D mm) 6 lbs (2.7 kg)	Same
Post Injection Readout	Displayed on Powerhead and Console	Same
OEM Interface	Available Via Relays and Optical Couplings / Serial (CAN)	Same
Safety Stop Mechanism	Electrical Stop When Injection Parameters are Out of Specification	Same
Volume Remaining Display	Displayed on Powerhead and Console	Same
Materials	Plastic and Metal	Same Plastic and Metal
Target Population	Humans	Same



Feature	OptiOne Single-Head Contrast Delivery System	OptiVantage DH Injector System with Enhanced Communication (K063503)
Sterility (Syringe)	Injectors are not sterile products, but syringes and disposables are provided sterile.	Same

VII. PERFORMANCE DATA

Extensive verification and validation activities were performed to ensure the OptiOne Single-Head Contrast Delivery System design outputs met all design inputs and the customer requirements were successfully met. The testing confirms the OptiOne Single-Head Contrast Delivery System meets the required specifications.

The OptiOne Single-Head Contrast Delivery System was also tested in conformance to the following recognized standards:

Standard
IEC ISO 14971 Second edition 2007-03-01 Application of Risk Management to Medical Devices
ISO 15223-1 Second Edition 2012-07-01 Medical Devices - Symbols to be Used with Medical Device Labels, Labelling, and Information to be Supplied - Part 1
AAMI / ANSI ES60601-1:2005/(R)2012 and C1:2009/(R)2012 and, a2:2010/(r)2012 Medical Electrical Equipment -- Part 1: General Requirements for Basic Safety and Essential Performance
IEC 60601-1-2 Edition 4.0 2014-02 Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests
IEC 60601-1-6 Edition 3.1 2013-10 Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability
IEC 62304 First Edition 2006-05 Medical Device Software - Software Life Cycle Processes. (Software/Informatics)
IEC 62366 Edition 1.1 2014-01 Medical Devices - Application of Usability Engineering to Medical Devices. (General I)



VIII. CONCLUSIONS

The OptiOne Single-Head Contrast Delivery System was developed under the Liebel-Flarsheim Company LLC Design Control processes. The verification and validation activities ensure the OptiOne meets all customer requirements and product specifications. The OptiOne Single-Head Contrast Delivery System has the same intended use as its predicate. The powerhead and software was modified from the predicate device to reflect the clinical use of a single head contrast delivery system from a dual head injector. Based on the data contained in this submission, Liebel-Flarsheim Company LLC believes the OptiOne Single-Head Contrast Delivery System is substantially equivalent to its predicate.