DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 27, 2017

Ecomed Solutions, LLC
% Christina Henza
Regulatory
Ultra Lifescience Solutions, Inc
146 N. Greenview Ave
Mundelein, Illinois 60060

Re: K162088
Trade/Device Name: Ecomed Disposable Angiographic Syringes
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector And Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: December 26, 2016
Received: December 28, 2016

Dear Christina Henza:

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,

Fernando Aguel -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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)*
K162088

Device Name
Ecomed Disposable Angiographic Syringes

Indications for Use *(Describe)*
The product is a family of Angiographic Syringes for the injection of contrast media and saline. The syringe is for single use with US legally marketed angiographic injectors.

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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510 (K) SUMMARY FOR ECOMED DISPOSABLE ANGIOGRAPHIC SYRINGES

1. DATE PREPARED: JAN 23, 2016

2. SUBMITTTER/ 510(K) HOLDER

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3. DEVICE NAME

Proprietary Name:	Ecomed Disposable Angiographic Syringes
Common/Usual Name:	Angiographic Syringes
Classification Name:	Injector and Syringe, Angiographic
Device Class:	DXT
Product Code:	21 C.F.R. § 870.1650

4. PREDICATE DEVICES

The following legally marketed medical devices have been identified as predicates:

Primary Predicate:

- Disposable Angiographic Syringes (WeiGao) K082439

Reference Devices:

- Optistar Elite Injection System K073592
- Syringe with Handi-fil K082212
- Medrad Mark V Plus Injector K903390

5. DEVICE DESCRIPTION

The Ecomed Disposable Angiographic Syringes are disposable syringes for use with contrast delivery systems that deliver contrast media or saline into the vascular system for the purpose of obtaining enhanced diagnostic images. The syringes are available in several sizes and configurations to ensure compatibility with US legally marketed contrast delivery systems.

The syringes are provided in kits that are configured from the following list of components:

- Syringe(s)
- Fill tube

- Vial Spike (small/large)
- Transfer tubing set (length, y vs straight)

Kit Contents:

Ecomed Kit Number	Kit Contents	Maximum Pressure	Compatible System
ECO-200360	150mL syringe J shaped Fill tube (7.2 inch)	1200 psi	Angiomat
ECO-100150	150mL syringe J shaped Fill tube (7.2 inch)	1200 psi	Mark IV and Mark V Plus
ECO-200801	60 mL Syringe Y-type transfer tubing set (90 inch) large spike (3 inch)	300 psi	Optistar Elite and Optistar LE
ECO-200800	(2) 60 mL syringes Y-type transfer tubing set (90 inch) large spike, small spike (3 inch)	300 psi	Optistar Elite and Optistar LE

6. INDICATIONS FOR USE

The product is a family of Angiographic Syringes for the injection of contrast media and saline. The syringe is for single use with US legally marketed angiographic injectors.

7. PRINCIPLES OF OPERATION

The principle of operation of the proposed Ecomed Disposable Angiographic Syringes are identical to the predicates, with the only variation being that they have the ability to connect to different injector systems which are supported by the inclusion of associated reference devices.

The Ecomed Disposable Angiographic Syringes are connected to US commercially available injector systems Angiomat, Mark IV and Mark V Plus, Optistar Elite and Optistar LE

8. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF PROPOSED COMPARED TO THE PREDICATE DEVICE

The proposed Ecomed Disposable Angiographic Syringes are substantially equivalent in both function and use to the predicate device, K082439 (cleared on 03/23/2009). Reference devices K073592 (cleared on 05/07/20008), K082212 (cleared on 01/22/2009) and K903390 (cleared on 09/26/1990) are used to support dimensional variations from the predicate devices.

The predicate device and all of the reference devices are class II legally marketed devices as shown by the associated 510(k) numbers and clearance dates. All of the devices are disposable Angiographic Syringes for use with angiographic injectors, FDA product code DXT regulation number 870.1650.

All of the devices have the same intended use and primary technological characteristics. The different technological characteristics include dimensional differences between the syringes for the purpose of compatibility with different injectors. Comparison testing to reference devices Optistar Elite Injection

System cleared via K073592 (05/07/20008), Syringe with Handi-fil (Angiomat) K082212 (01/22/2009) and Medrad Mark V Plus Injector K903390 (09/26/1990) are used to support dimensional variations from the predicate devices. The different technological characteristics are included in the risk assessment and testing (see section 14, 15, and 18). No new questions of safety and effectiveness were introduced.

Table 1. Comparison of Ecomed Disposable Angiographic Syringes with Predicate Devices

Identification		Proposed Device	Predicate Device (Primary)	Reference Device 1	Reference Device 2	Reference Device 3
Name		Ecomed Disposable Angiographic Syringes	Disposable Angiographic Syringes (WeiGao)	Optistar Elite Injection System	Syringe with Handi-fil	Medrad Mark V Plus Injector
Regulatory Information	510(k)#	K162088	K082439	K073592	K082212	K903390
	Predicates	K082439	K072696	K984088	K963071	Unavailable
	Product Code	DXT	DXT	DXT	DXT	DXT
	Class	2	2	2	2	2
	Combination Product	No	No	No	No	No
	Regulation Number	870.1650	870.1650	870.1650	870.1650	870.1650
	Regulation Generic Name	Injector and Syringe, Angiographic	Injector and Syringe, Angiographic	Injector and Syringe, Angiographic	Injector and Syringe, Angiographic	Injector and Syringe, Angiographic
Intended use	Regulation Intended Use	"used to inject contrast material into the heart, great vessels, and coronary arteries to study the heart and vessels by x-ray photography."	"used to inject contrast material into the heart, great vessels, and coronary arteries to study the heart and vessels by x-ray photography."	"used to inject contrast material into the heart, great vessels, and coronary arteries to study the heart and vessels by x-ray photography."	"used to inject contrast material into the heart, great vessels, and coronary arteries to study the heart and vessels by x-ray photography."	"used to inject contrast material into the heart, great vessels, and coronary arteries to study the heart and vessels by x-ray photography."
	Indications	The product is a family of Angiographic Syringes for the injection of contrast media and saline. The syringe is for single use with US legally marketed angiographic injectors.	Disposable Angiographic Syringe is intended for the injection of contrast media or saline. This syringe is for single use with US legally marketed angiographic injectors.	The Optistar Elite Injection System is a contrast delivery system and is designed to inject MR contrast media and flushing solutions into a patient's vascular system to obtain diagnostic images when used with Magnetic Resonance Imaging equipment.	The Syringe with Handi-Fil is part of the contrast delivery system which is designed to inject radiopaque contrast media and/or saline into the vascular system for Angiographic or CT procedures as prescribed by qualified healthcare professionals	This device is intended to be used specifically for the purposes of injecting intravenous contrast medium into humans for diagnostic studies.

Identification		Proposed Device	Predicate Device (Primary)	Reference Device 1	Reference Device 2	Reference Device 3
Name		Ecomed Disposable Angiographic Syringes	Disposable Angiographic Syringes (WeiGao)	Optistar Elite Injection System	Syringe with Handi-fil	Medrad Mark V Plus Injector
Technology	Anatomical sites	Peripheral Intravenous	Peripheral Intravenous	Peripheral Intravenous	Peripheral Intravenous	Peripheral Intravenous
	Contact Type	External communicating device -blood path, indirect	External communicating device -blood path, indirect	External communicating device -blood path, indirect	External communicating device -blood path, indirect	External communicating device -blood path, indirect
	Contact duration	Limited ≤ 24 hours	Limited ≤ 24 hours	Limited ≤ 24 hours	Limited ≤ 24 hours	Limited ≤ 24 hours
	Biocompatibility	Biocompatible	Biocompatible	Biocompatible	Biocompatible	Biocompatible
	Storage conditions	General warehouse.	General warehouse.	General warehouse.	General warehouse.	General warehouse.
	Shelf Life	3 years	3 years	5 years	3 years	3 years
	Luer connectors	ISO 594 compliant	ISO 594 compliant	ISO 594 compliant	ISO 594 compliant	ISO 594 compliant
	Fill size	60mL 150 mL	60 mL 110mL 200mL	60mL	150mL 200mL	150mL
	Compatible injectors	Optistar Angiomat Mark IV and Mark V Plus	Stellant Spectris Solaris CT900 & CT900ADV Dual Shot CT	Optistar	Angiomat	Mark IV and Mark V Plus

9. SUMMARY OF NON-CLINICAL TESTING PERFORMANCE AS BASIS OF SUBSTANTIAL EQUIVALENCE

The performance standards listed below were used to demonstrate substantial equivalence of the proposed Ecomed Disposable Angiographic Syringes to the predicate device included in K082439 (cleared on 03/23/2009). Reference devices cleared via K073592 (cleared on 05/07/20008), K082212 (cleared on 01/22/2009) and K903390 (cleared on 09/26/1990) are used to support dimensional variations from the predicate devices and confirmation of equivalence is shown by comparison testing.

Non-clinical performance (bench) tests conducted on the subject devices to support substantial equivalence includes comparison testing and physical performance testing. Comparison testing was performed at T=0 to demonstrate dimensional compatibility with competitive syringe delivery systems by verifying the key physical dimensions that interact with the syringe delivery system (Barrel and Plunger dimensions). Physical Performance testing includes leak testing and an examination of fill tube diameters and extension tube diameters which are shown by the results to be stable over the T=1, T=2, and T=3 test intervals.

Testing was performed to verify compliance of the Ecomed Disposable Angiographic Syringes with the following standards:

- ISO 11135-1 sterilization of health-care products - ethylene oxide - requirements for the development, validation and routine control of a sterilization process for medical devices. (Sterility)
- ISO 11607-1 packaging for terminally sterilized medical devices - part 1: requirements for materials, sterile barrier systems and packaging systems [including: amendment 1 (2014)]. (Sterility)
- ASTM F1980-07 (Reapproved 2011), standard guide for accelerated aging of sterile barrier systems for medical devices. (Sterility)
- ISO 10993-1 (2009), "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"
- ISO 10993-5 (2010), "Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 (2009), "Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization"
- ISO 10993-11 biological evaluation of medical devices - part 11: tests for systemic toxici-ty. (Biocompatibility)
- USP <151> pyrogen test (usp rabbit test). (Sterility)
- ASTM F756-13 standard practice for assessment of he-molytic properties of materi-als. (Biocompatibility)
- ISO 7886-1 sterile hypodermic syringes for single use - part 1: syringes for manual use [includ-ing: technical corrigendum 1 (1995)]. (General Plastic Surgery/General Hospital
- ISO 594-1 conical fittings with a 6% (luer) taper for syringes, needles and certain other med-ical equipment - part 1: general require-ments. (General Plastic Surgery/General Hospital)
- ISO 14971 (2007), "Medical Devices-Risk Management, Part 1: Application of Risk Analysis to Medical Devices"

The results of this testing as confirm that the Ecomed Disposable Angiographic Syringes are substantially equivalent to the predicate and reference devices.

10. CONCLUSION DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

Based on the information and supporting documentation provided in the premarket notification, the Ecomed Disposable Angiographic Syringes are substantially equivalent to the cited predicate devices.

Testing demonstrates that the Ecomed Disposable Angiographic Syringes fulfill prospectively defined design and performance specifications.