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,

[Signature]

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
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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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
510 (K) SUMMARY FOR ECOMED DISPOSABLE ANGIOGRAPHIC SYRINGES

1. DATE PREPARED: JAN 23, 2016

2. SUBMITTTER/ 510(K) HOLDER
Ecomed Solutions, Inc.
214 Terrace Drive, Mundelein, IL 60060
Primary Contact: David Yurek
david.yurek@ecomed-solutions.com
Telephone: 866-817-7114
Fax: 847-984-9286

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:

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

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 (05/07/2008), 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>
<thead>
<tr>
<th>Identification</th>
<th>Proposed Device</th>
<th>Predicate Device (Primary)</th>
<th>Reference Device 1</th>
<th>Reference Device 2</th>
<th>Reference Device 3</th>
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<tbody>
<tr>
<td><strong>Name</strong></td>
<td>Ecomed Disposable Angiographic Syringes</td>
<td>Disposable Angiographic Syringes (WeiGao)</td>
<td>Optistar Elite Injection System</td>
<td>Syringe with Handi-Fil</td>
<td>Medrad Mark V Plus Injector</td>
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<td><strong>Regulatory Information</strong></td>
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<td>510(k)#</td>
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<td>Regulation Intended Use</td>
<td>“used to inject contrast material into the heart, great vessels, and coronary arteries to study the heart and vessels by x-ray photography.”</td>
<td>“used to inject contrast material into the heart, great vessels, and coronary arteries to study the heart and vessels by x-ray photography.”</td>
<td>“used to inject contrast material into the heart, great vessels, and coronary arteries to study the heart and vessels by x-ray photography.”</td>
<td>“used to inject contrast material into the heart, great vessels, and coronary arteries to study the heart and vessels by x-ray photography.”</td>
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<tr>
<td><strong>Indications</strong></td>
<td>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.</td>
<td>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.</td>
<td>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.</td>
<td>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.</td>
<td>This device is intended to be used specifically for the purposes of injecting intravenous contrast medium into humans for diagnostic studies.</td>
</tr>
<tr>
<td>Identification</td>
<td>Proposed Device</td>
<td>Predicate Device (Primary)</td>
<td>Reference Device 1</td>
<td>Reference Device 2</td>
<td>Reference Device 3</td>
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<tr>
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<td>Disposable Angiographic Syringes (WeiGao)</td>
<td>Optistar Elite Injection System</td>
<td>Syringe with Handi-fil</td>
<td>Medrad Mark V Plus Injector</td>
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<td>External communicating device -blood path, indirect</td>
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<td>150 mL</td>
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<td></td>
<td>200mL</td>
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<tr>
<td>Compatible injectors</td>
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<td>Stellant Spectris Solaris CT900 &amp; CT900ADV Dual Shot CT</td>
<td>Optistar Angiomat</td>
<td>Mark IV and Mark V Plus</td>
<td></td>
</tr>
</tbody>
</table>

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 05/07/2008), 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 10993-11 biological evaluation of medical devices - part 11: tests for systemic toxicity. (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 [including: 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)

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.