July 7, 2015

Jiangsu Yile Medical Article Co., Ltd  
C/O Mr. Charles Mack  
Principal Engineer  
International Regulatory Consulting  
12226 Washington Lane  
Parker, AZ 85344

Re: K143070  
Trade/Device Name: Disposable Safety Self-destructive Syringes, 5ML  
Regulation Number: 21 CFR 880.5860  
Regulation Name: Piston syringe  
Regulatory Class: II  
Product Code: MEG, FMI  
Dated: May 27, 2015  
Received: June 04, 2015

Dear Mr. Mack:

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” (21CFR 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,

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH
FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use (Describe)

The Disposable Safety Self-destructive Syringe is used to inject fluids into, or withdraw fluids from the body. In addition, it is designed to aid in the prevention of needle stick injuries.

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.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
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

This summary of 510(k) information is being submitted in accordance with requirements with requirements of CFR Part 807.92.

Date:  June 24, 2015

1. Company and Correspondent making the submission:
   Name - Jiangsu Yile Medical Article Co., Ltd
   Address - Sanhekou Development Zone, Changzhou City Jiangsu Province
   China 213115
   Tel:  86-519-88675299
   Fax: 86-519-88679018
   Contact - Mr. Feng Xingyuan
   General Manager
   Email - charliemack@irc-us.com

   Primary contact and correspondent:
   Name: Charles Mack
   Address: 12226 Washington Lane, Parker, Arizona 85344
   Phone" 931-625-4938
   Email: charliemack@irc-us.com

2. Device :
   Trade/proprietary name: Disposable Safety Self-destructive Syringes, 5ML
   Common Name : Syringe, Antistick; needle; hypodermic, single lumen
   Classification Name : Piston syringe, Hypodermic single lumen needle

3. Predicate Devices :
   InviroSnap Safety Syringe 1ML, 3ML, 5ML, 10ML, 20ML, (K092430)

4. Classifications Names & Citations :
   21CFR 880.5860, MEG, syringe, antistick; 21CFR880.5570, FMI, needle, hypodermic, single lumen; both classifications are Class 2
5. Description:

The JIANGSU YILE MEDICAL ARTICAL C0., LTD Disposable Safety Self-destructive Syringes, 5MLs are single lumen hypodermic needles with a safety mechanism to prevent needle stick after the usage. The Disposable Safety Self-destructive Syringe is used to inject fluids into, or withdraw fluids from the body. In addition, it is designed to aid in the prevention of needle stick injuries.

The syringes are made of a protector, needle, up connector, 0-ring seal, down connector, barrel, piston and plunger. The syringe and body are constructed of Polypropylene (PP). The piston and 0-ring seal are made of natural rubber. Lumens are constructed of 304 Stainless Steel.

6. Indication for use:

The Disposable Safety Self-destructive Syringe is used to inject fluids into, or withdraw fluids from the body. In addition, it is designed to aid in the prevention of needle stick injuries.

7. Technological Characteristics and Comparison with predicate device:

Jiangsu Yile Medical Article Co., Ltd believes that the Disposable Safety Self-destructive Syringes, 5ML are substantially equivalent to the InviroSnap Safety Syringe 1ML, 3ML, 5ML, 10ML, 20ML (K092430).

Please note the comparison table on the following page, which demonstrates the similarities of the Jiangsu Yile Medical Article Co., Ltd Disposable Safety Self-destructive Syringes, 5MLs and the predicate device.
<table>
<thead>
<tr>
<th>Element of comparison</th>
<th>Subject Device</th>
<th>Claimed SE Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company</td>
<td>JIANGSU YILE MEDICAL ARTICLE CO., LTD</td>
<td>INVIRO MEDICAL DEVICES, INC.</td>
</tr>
<tr>
<td>FDA510(K) Number</td>
<td>K143070</td>
<td>K092430</td>
</tr>
<tr>
<td>Device Name</td>
<td>Disposable Safety Self-destructive Syringes, 5ML</td>
<td>InviroSnap Safety Syringe</td>
</tr>
<tr>
<td>Model Number</td>
<td>5ML</td>
<td>1, 3, 5, 10 and 20ML</td>
</tr>
<tr>
<td>Intended Use</td>
<td>The Disposable Safety Self-destructive Syringe is used to inject fluids into, or withdraw fluids from the body. In addition, it is designed to aid in the prevention of needle stick injuries.</td>
<td>The InviroSnap Safety Syringe is used to inject fluids into, or withdraw fluids from, the body. In addition, the InviroSnap Safety Syringe is designed to aid in the prevention of needle stick injuries.</td>
</tr>
<tr>
<td>Principle of operation</td>
<td>Identical</td>
<td>After use, the health care professional fully depresses the plunger to engage the luer assembly. Once the luer assembly is engaged, pulling back the plunger causes the Adapter and the attached needle to be withdrawn into the safety of the barrel. In this position against the flange, lateral pressure on the plunger results in a controlled fracture of the plunger. Both the syringe and plunger are discarded in a sharps container.</td>
</tr>
<tr>
<td>Safety feature</td>
<td>Identical</td>
<td>Manually retractable safety syringe with permanent disable</td>
</tr>
<tr>
<td><strong>Material</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Barrel</td>
<td>PP</td>
<td>PP</td>
</tr>
<tr>
<td>Plunger</td>
<td>PP</td>
<td>PP</td>
</tr>
<tr>
<td>Piston</td>
<td>Natural Rubber</td>
<td>Natural Rubber</td>
</tr>
<tr>
<td>Needle</td>
<td>Stainless Steel</td>
<td>Stainless Steel</td>
</tr>
<tr>
<td>Needle Protector</td>
<td>PP</td>
<td>PP</td>
</tr>
<tr>
<td>Lubricant</td>
<td>Polydimethylsiloxane Oil</td>
<td>Silicone Oil</td>
</tr>
<tr>
<td>Specific drug use</td>
<td>Identical</td>
<td>Conventional drugs</td>
</tr>
<tr>
<td>Sterilization</td>
<td>Identical</td>
<td>EO Sterilization</td>
</tr>
<tr>
<td>Needle length</td>
<td>1 1/2 Inch</td>
<td>1 1/4 Inch</td>
</tr>
<tr>
<td>Needle gauge</td>
<td>21G</td>
<td>21/22/23G</td>
</tr>
<tr>
<td>Needle tip configuration</td>
<td>Identical</td>
<td>Tri-Beveled Tip</td>
</tr>
<tr>
<td>Wall type</td>
<td>Identical</td>
<td>Regular wall</td>
</tr>
<tr>
<td>Nozzle type</td>
<td>Identical</td>
<td>Needle and hub are separated to the syringe</td>
</tr>
<tr>
<td>Barrel marking specs</td>
<td>Identical</td>
<td>Conforms to ISO 7886-1</td>
</tr>
<tr>
<td>Gradations legibility</td>
<td>Identical</td>
<td>0.2ml</td>
</tr>
<tr>
<td>Needle cover color</td>
<td>Identical</td>
<td>Clarity</td>
</tr>
<tr>
<td>Lubricant composition</td>
<td>Polydimethylsiloxane Oil</td>
<td>Silicone Oil</td>
</tr>
<tr>
<td>Lubricant amount/cm²</td>
<td>Identical</td>
<td>&lt;0.25mg/cm²</td>
</tr>
<tr>
<td>Barrel transparency</td>
<td>Identical</td>
<td>Transparency</td>
</tr>
<tr>
<td>Delivery accuracy</td>
<td>Identical</td>
<td>Conforms to ISO 7886-1</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>Identical</td>
<td>Conform to ISO 10993-1</td>
</tr>
<tr>
<td>Syringe type</td>
<td>Identical</td>
<td>Antistick syringe</td>
</tr>
<tr>
<td>Reuse</td>
<td>Identical</td>
<td>Single use only</td>
</tr>
<tr>
<td>Sterility</td>
<td>Identical</td>
<td>Sterile</td>
</tr>
</tbody>
</table>
8. Non-clinical and Performance Tests:

List the actual tests performed on the subject device

**Biocompatibility:**
- Cytotoxicity Test (ISO10993-5: 2009)
- Sensitization Test (ISO10993-10: 2010)
- Intracutaneous Reactivity Test (ISO10993-10: 2010)
- Hemolysis Test (ASTM F756-13)

**Performance:**
- ISO 7864:1993 Sterile hypodermic needles for single use
- ISO 9626: 2001 Stainless steel needle tubing for the manufacture of medical devices
- ISO 23908: 2011 Sharps injury protection-requirements and test methods-sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
- ISO 7886-4:2006 Sterile hypodermic syringes for single use-Part 4: Syringes with re-use
- ISO 594/1, Conical fittings with a 6% (luer) taper for syringes, needles and certain other medical equipment - part 1: general requirements.
- ISO 594-2 Second edition 1998-09-01, Conical fittings with a 6% (luer) taper for syringes, needles and certain other medical equipment - part 2: lock fittings.
- USP 788 Light Obscuration Particle Count Test

**Simulated clinical use:**
- FDA guidance “Guidance for industry and FDA Staff, Medical Devices with Sharps Injury Prevention Features, August 9, 2005”.

**Package and Shelf Life:**
- Real Time Stability Test
- Accelerated Aging Test
- Sterile test
- Vacuum leak test
- Dye penetration test
- Agar contact-attack test (Microbial barrier properties)
- Tensile Seal Strength Test

Related standards:
- ASTM F88 -09 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ISO 23908: Sharps injury protection-requirements and test methods-sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
- ISO7864: Sterile hypodermic needles for single use.

All test results were satisfactory.
9. Conclusions:
In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Jiangsu Yile Medical Article Co., Ltd concludes that the Disposable Safety Self-destructive Syringes, 5ML are substantially equivalent to predicate devices as described herein.

END