K123710

MAY 9 2013

Bio-Med USA Inc UniTox®Syringe

Summary of safety and effectiveness

In accordance with Section 513(1) of the SMDA as defined in 21CFR part 807.3, This summary is submitted to obtain Premarket 510(K) notification

1. Submitter
Mr. Young Chi.
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2. Name of Medical Device
Trade name : UniTox® Syringe
Classification name : Piston Syringe
Regulation : 880.5860
Class : II
Product code : FMF/FMI

3. Substantial Equivalence (Identification of legally Marketed Device)
The UniTox ® Syringe are substantially equivalent in Design, Function, Performing and all used material to already cleared DMJECT Uni-body Insulin Syringe by K993017, and other several needle permanently attached Insulin Syringe, but different graduate to use Botox®Cosmetic..

4. Device Description

UniTox® Syringe are sterile, single use, disposable hypodermic syringes with a permanently affixed lumen needle to the tip of syringe. The syringe consists of a barrel, a plunger rod with Synthetic Rubber Gasket, and yellow colored end-cap over the needle to preserve sterility of the fluid path.
In addition the UniTox ® Syringe are pyrogen free, and available , 0.5cc (20units), 30G X 5/16"needle length and conformed following standard (graduate drawing attached)

ISO 7864 Sterile, Hypodermic Needles for single use
ISO 8537: second edition,: 2007 Sterile, Single use Syringe with/without needle

5. Device Intended use

UniTox Syringe is single use, sterile, intended use for the subcutaneous injection of Botox®Cosmetic into parts of body below the surface of skin.

6 Summary of Technological characteristics.

UniTox® Syringe are the same function, performing as those currently on market in permanently needle attached uni-body insulin syringe, and there are no difference in technological characteristic between the UniTox® Syringe and cited predicate device, only has different graduate (mark) to use Botox®Cosmetic.
accordingly, no any new issues of safety or effectiveness raised.
This device operates on principles of piston syringe.

7 Packaging and Labeling

The UniTox® Syringe is sterilized, and packed in blister individually, and one hundred blister packs are packed in a Chipboard box, and also provided 10 sterilize syringe in a poly bag, 10 poly bags in a Chipboard box. Each blister pack, poly bag and Chipboard box are labeled with the contents and appropriate information per the FDA's quality systems regulation and labeling requirement (21 CFR part 801)

- Inner box drawing sample attached
- 10pcs poly bag, Individual blister, Graduate mark drawing attached

8. Biocompatibility certify

UniTox® Syringe using exact same raw material, which has been previously tested and accepted Biocompatibility, and also manufactured with same process as already cleared Predicate Device DM JECT, SUREJECT uni-body insulin syringe K993017,.so additional Biocompatibility testing to ISO10993 standard is not required

Conclusion

The UniTox® Syringe submitted in this Pre-market notification is substantially equivalent to the DMJECT, SUREJECT insulin syringe cleared K993017 in respect to design, used material, producing process, Technology / Principle of Operation and Performance. Differences between the devices do not raise any new issues of safety or effectiveness.

End of Summary

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

May 9, 2013

Mr. Young Chi
President
BioMed USA, Incorporated
111 Ellison Street
PATTERSON, NJ 07505

Re: K123710
Trade/Device Name: UniTox® Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF, FMI
Dated: March 25, 2013
Received: April 8, 2013

Dear Mr. Chi

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.

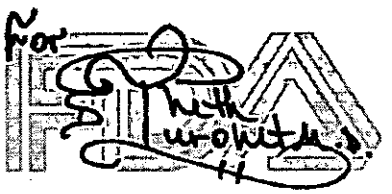
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Bio-Med USA Inc.

510(K) submission **UniTox® Syringe**

Indication for use statement

510(K) Nr K 123710

Device Name : UniTox® Syringe

Indication for use : Single use, Sterilized, Intended use for the subcutaneous injection of Botox®Cosmetic into parts of body below the surface of skin.

Prescription use ___XX___ or/and Over the counter _____
Part 21CFR 801 Sub part D 21CFR 801 Sub part C

PLEASE DO NOT USE BELOW THE LINE- CONTINUED ANOTHER PAGE IF NEEDED

Concurrence of CDRH, office of Device Evaluation (OED)

FDA

Richard C. Chapman
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K123710

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