### Sec. 6: 510(k) Summary – Global Medi Products Retractable Safety Syringe

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<th>Date Summary was Prepared</th>
<th>October 17, 2012 rev1.</th>
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| **Device Common Name**     | Syringe, Antistick |
| **Trade Name**             | Global Medi Products Retractable Safety Syringe |
| **Device Product Codes and Classification Name** | MEG, 21CFR880.5860, Piston Syringe  
FMI, 21CFR880.5570. Needle, Hypodermic, Single Lumen |
| **Predicate Device**       | M.K. MEDITECH CO. LTD, DUOPRO SAFETY SYRINGE (DUOPROSS) K022806 |

**Device Description**

The Global Medi Products Retractable Safety Syringe is a sterile, single use, disposable and non-reusable device intended for medical purposes that consists of a calibrated hollow barrel and a movable plunger. At one end of the barrel there is a male luer lock connector (nozzle) for fitting the female luer connector (hub) of a hypodermic single lumen needle. Note: the 1ml Retractable Safety Syringe has an integral 25G x 1" hypodermic single lumen needle. The device is used to inject fluids into, or withdraw fluids from, the body. The function of the Global Medi Products Retractable Safety Syringe works the same as a conventional hypodermic syringe except for its ability to retract the contaminated needle inside the syringe immediately after patient injection. Needle retraction is activated by the syringe user. Because the needle is manually withdrawn into the syringe barrel, the syringe user is protected from accidental needle sticks. These accidental needle sticks could occur between removing the needle from the patient and disposing of the syringe in a sharps disposal container.

The Global Medi Products Retractable Safety Syringe is packaged, sterilized and delivered in a ready to use condition. It is not compatible with, and is not intended to be used with any other needles or syringe accessories.

The syringe barrel, plunger, needle base, needle cap, needle base cap are manufactured from medical grade polypropylene and tested for biocompatibility. The piston, seal and o-ring are manufactured from medical grade rubber and also tested for biocompatibility. The needle assemblies are manufactured from AISI 304 stainless steel and documented as biocompatible.

The operating principles and method for the Global Medi Products Retractable Safety Syringe is substantially equivalent to the predicate device. The needle is retracted manually and enclosed within the syringe barrel one the injection has been completed. Once the plunger is fully retracted and ‘snapped’ off the device is rendered non-reusable. Differences between the Global Medi Products Retractable Safety Syringe and the predicate device are (1) Global Medi Products are sterilized via validated ETO gas sterilization process to a $10^{-6}$ SAL, as is the predicate device, (2) there are minor dimensional differences, these dimensional differences do not affect performance or raise new issues of safety and effectiveness.
Intended Use

Indications for Use: The Global Medi Products Retractable Safety Syringe is a sterile, single use, disposable and non-reusable manual retractable safety syringe intended for medical purposes for injection of fluids into the body, while reducing the risks of sharps injuries and the potential for syringe reuse.

Technological Characteristics

Global Medi Products makes the claim of substantial equivalence of the GMP Retractable Safety Syringe to the Meditech Co. DuoProSS Retractable Safety Syringe based on similarities in intended use, design, technological, and operational characteristics. Both are indicated for injecting fluids into the body, while helping to reduce risks of sharps injuries. The GMP Retractable Safety Syringe are always provided with preassembled needs whereas the DuoProSS can be ordered with and without needles. GMP Retractable Safety Syringe currently uses a male luer lock needle connector design where the DuoProSS uses a luer slip ne connector design. Both syringes are provided sterile, single use, and disposable. There are minor differences between the GMP Retractable Safety Syringe and DuoProSS which is syringe volume (and associated dimensions). This difference does not affect the performance of the syringe, since syringe size is typically determined by drug volume to be administered and user preferences. Both syringes have two part plungers. The distal part holds the hypodermic needle and the proximal part has a projection spike that mates with the distal part, thereby locking the needle to the plunger. Both syringes require the user to manually retract the needle-plunger into the syringe barrel, break of the plunger rod, and discard the pieces. Global Medi Products believes that the differences between the GMP Retractable Safety Syringe and the predicate device are minor and they raise no new issues of safety or effectiveness.

Summary of Testing


Substantial Equivalence

The Retractable Safety Syringe described in this 510(k) submission is substantially equivalent in all specifications and performance compared to the predicate device indentified in K022806.
Global Medi Products  
C/O Robert O. Dean  
President  
Compliance Systems International, Limited Liability Company  
1083 Delaware Avenue  
Buffalo, New York 14209

Re: K120641  
   Trade/Device Name: Global Medi Products Retractable Safety Syringe  
   Regulation Number: 21 CFR 880.5860  
   Regulation Name: Piston Syringe  
   Regulatory Class: II  
   Product Code: MEG  
   Dated: October 10, 2012  
   Received: October 16, 2012

Dear Mr. Dean:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance. 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 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,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Indications for Use Form

Indications for Use:

510(k) Number (if known): K120641

Device Name: Global Medi Products Retractable Safety Syringe

Indications for Use: The Global Medi Products Retractable Safety Syringe is a sterile, single use, disposable and non-reusable manual retractable safety syringe intended for medical purposes for injection of fluids into the body, while reducing the risks of sharps injuries and the potential for syringe reuse.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

[Signature]
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120641