K111734

SEP - 6 2011

10. 510(k) Summary

This Summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

10.1.	**Submitter's Name :**	MedicalChain International Corp.
	Address :	No. 413, Ming-Hsouie Rd., Taipei, Taiwan
	Tel :	886-2-25322825
	Fax :	886-2-25636489
	Contact Person :	Ms. Lin Lee, Lee / President
	510 (k) Owner :	MedicalChain International Corp.
	Summary Prepared Date :	June 15, 2011
10.2.	**Device Name :**	*MySafety*® **Syringe**
	Trade Name : (Proprietary Name)	*MySafety*® **Syringe**
	Common Name :	Safety Syringe (with attached needle)
	Classification Name :	Piston Syringe / Anti-Stick Syringe
	Classification :	Class II
	Regulatory Number :	21 CFR 880.5860
	Product Code :	MEG
10.3.	**Predicate Device :**	" **IN6 SAFETY SYRINGE MODEL 3ML** ", 510(k) Number : K051800 marketed by MedicalChain International corp.

10.4. Device Description :

The device description of the submitted device *MySafety*® **Syringe** is as follows.

The submitted device *MySafety*® **Syringe** is a 1cc / ml size, sterile, single-use, disposable, non-reusable, needle-retractable, piston syringe, provided with an attached needle , which is intended for the injection of medication into a patient, while minimizing the potential for accidental injury as a result of needle-stick (sharps injury) and preventing syringe reuse.

The submitted device *MySafety*® **Syringe** works like a conventional hypodermic syringe except for its ability to retract the used needle inside the syringe barrel at the end of injection. The needle retraction mechanism is activated as the following.

"After injection is completed, remove the syringe from patient's body, add pressure to the plunger by pushing the plunger further ahead with one hand till you hear a clear audible "click" sound and you see the needle fully retracted into the syringe barrel."

The submitted device *MySafety*® **Syringe** is a smaller version of is *MySafety*® **Syringe** 3cc / ml which was originally cleared as " **IN6 SAFETY SYRINGE MODEL 3ML** ", 510(k) Number : K051800. The submitted device *MySafety*® **Syringe** is comparable to the *MySafety*® **Syringe** 3cc / ml; there is no significant change with regards to the intended use, the fundamental scientific technology, and the materials. Only the specification, such as capacity of volume, differs.

10.5. Intended Use :

The submitted device *MySafety*® **Syringe** is designed as an anti-stick syringe to reduce the risk of sharps injuries and the potential for syringe re-use and is a single use, disposable and retractable safety syringe which is intended for injection of medical fluids into the body.

10.6. Technological Characteristics

The submitted device *MySafety*® **Syringe** has the same technological characteristics as the predicate device 510(k) Number : K051800 , as below.

(1). The intended use for injecting medication into patient's body, while helping to reduce the risk of sharps injuries and syringe reuse.

(2). The spring-based retracting mechanism.

(3). The safety mechanism is activated by one hand.

(4). The used needle is fully retracted into the syringe.

(5). The mode of operation

(6). The materials of the syringe and needle.

(7). The components of the syringe including syringe barrel, plunger, piston, needle, needle hub, needle protector, spring and O-Ring.

10.7. Substantial Equivalence :

MedicalChain International Corp. makes a Substantial Equivalence claim of the submitted device *MySafety*® **Syringe** to the original cleared 510(k) Number : K051800 based on similarities in intended use, design, technological, functional and performance characteristics.

A side-by-side Substantial Equivalence Comparison Table of the submitted device *MySafety*® **Syringe** with the original cleared 510(k) Number : K051800 is provided in Section 8.1.

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10.8. Conformance of Standards Summary Report :

In terms of Physical Specification, Chemical Specification, Biological Specification, Packaging & Sterilization Specification, the submitted device conforms to applicable standards as describing in a Conformance of Standards Summary Report which includes information on all standards utilized during the development of the submitted device as follows.

Conformance of Standards Summary Report

	Standard Numeric ID	Standard Title	Adaptation		Selection of Methods		Deviations		Requirement N/A		*3rd Party Test Lab	
			Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
1	ISO 6009 : 1992	Hypodermic needles for single use -- Color coding for identification		V		V		V		V		V
2	ISO 7864 : 1993	Sterile hypodermic needles for single use		V		V		V		V		V
3	ISO 7886-1 : 1993	Sterile hypodermic syringes for single use		V		V		V		V		V
4	ISO 9626 : 1991	Stainless steel needle tubing for manufacture of medical devices		V		V		V		V		V
5	ISO 10993-1 : 2009	Biological evaluation of medical devices-- Part 1 : Evaluation and testing		V		V		V		V	V	
6	ISO 10993-4 : 2002	Biological evaluation of medical devices-- Part 4 : Selection of tests for interaction with blood		V		V		V		V	V	
7	ISO 10993-5 : 2009	Biological evaluation of medical devices-- Part 5 : Tests for cytotoxicity: in vitro		V	V			V		V	V	
8	ISO 10993-7 : 2008	Biological evaluation of medical devices-- Part 7 : Ethylene oxide sterilization		V		V		V		V	V	
9	ISO 10993-10 : 2010	Biological evaluation of medical devices-- Part 10 : Tests for irritation and skin sensitization		V		V		V		V	V	
10	ISO 10993-11 : 2006	Biological evaluation of medical devices-- Part 11 : Tests for systemic toxicity		V		V		V		V	V	
11	ISO 11135-1 : 2007	Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical		V	V			V		V		V
12	ISO 11607-1 : 2006	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and		V		V		V		V		V
13	ISO 14971 : 2007	Medical devices--Application of risk management to medical devices		V		V		V		V		V
14	ISO 15223-1 : 2007	Medical devices--Symbols to be used with medical device labels, labeling and information to be supplied		V		V		V		V		V
15	USP 33 : 2010<151>	Pyrogen Test (USP Rabbit Test)		V		V		V		V	V	

* The 3rd party test laboratory used by MCI is TüV SüD PSB Pte Ltd, 1 Science Park Drive, Singapore 118221.

A Declaration of Conformity with Design Controls is provided in Attachment 5.

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10.9. Conclusion :

The submitted device *MySafety*® **Syringe** has the same intended use, technological characteristics, materials, performance and indications as the originally cleared 510(k) Number : K051800 . The submitted device *MySafety*® **Syringe** does not raise any new questions of safety or effectiveness. Thus, the submitted device *MySafety*® **Syringe** is substantially equivalent to the originally cleared as K051800.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MedicalChain International Corporation
C/O Mr. Robin Hwang
Consultant
ICP Consulting Corporation
1808 Seabreeze Court
Thousand Oaks, California 91320

SEP - 6 2011

Re: K111734
Trade/Device Name: MySafety® Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: August 8, 2011
Received: August 10, 2011

Dear Mr. Hwang:

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" (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,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

6. Statement of Indications for Use

510(K) Number (if known): K111734

Device Name : *MySafety*® **Syringe**

Indications For Use:

The *MySafety*® **Syringe** is designed as an anti-stick syringe to reduce the risk of sharps injuries and the potential for syringe re-use and is a single use, disposable and retractable safety syringe which is intended for injection of medical fluids into the body.

Prescription Use ___X___ AND / OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

9/6/11
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111734