510(K) SUMMARY

JUL 2 2 2014

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: **K130097**

1. **Submitters Identification:**

Contact Person: Mike Hoftman

Address: Advanced Medical Innovations, Inc
8741 Shirley Avenue, Northridge, CA 91324

Tel: 818-701-7180

Fax: 818-701-9708

Date Prepared: December 12, 2012

2. **Name of the Device:** MedMate™ Guarded (18g) Needle
3. **Common Name:** Hypodermic single lumen needle

Regulation: 880.5570

Product Code: FMI

4. **Predicate Device Information and Comparison:**

Device Description 510(k) #: K130097	Predicate Device	510(k) Number	Comparison
The MedMate™ Guarded (18g) Needle is used for general purpose injection and aspiration of fluid from vials and ampoules.	The BD Eclipse Hypodermic Needle used for general purpose injection and aspiration of fluid from vials, ampoules and parts of the body below the surface of the skin.	**K010188**	The subject device is basically identical to the predicate device with respect to technological characteristics and function.

5. **Device Description:**

   Advanced Medical Innovations Guarded (18g) Needle is used for general purpose injection and aspiration of fluid from vials and ampoules.

6. **Intended and Indication for Use:**

   The MedMate™ Guarded (18g) Needle is used for general purpose injection and aspiration of fluid from vials and ampoules. The device features a shield that prevents accidental needle sticks.

   The MedMate Guarded Needle is compatible for use with standard luer-slip and luer-lock syringes.

7. **Discussion of Non-Clinical Tests Performed for the Determination of Substantial Equivalence are as follows:**

   No non-clinical tests were performed.

8. **Discussion of Clinical Tests Performed:**

   Clinical testing was not performed.

9. **Conclusions:**

   Based on the information provided in this submission we conclude that the MedMate Guarded Needle is substantially equivalent to the predicate and is safe and effective for its intended use.

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

July 22, 2014

Advanced Medical Innovations, Incorporated
Mr. Mike Hoftman
President
8741 Shirley Avenue
Northridge, CA 91324

Re: K130097
Trade/Device Name: MedMate™ Guarded (18g) Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: II
Product Code: FMI
Dated: June 5, 2014
Received: June 11, 2014

Dear Mr. Hoftman:

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,

Mary S. Brimer -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K130097

Device Name
The MedMate Guarded (18g) Needle

Indications for Use *(Describe)*
The MedMate Guarded (18g) Needle is used for general purpose injection and aspiration of fluid from vials and ampoules.

The MedMate Guarded Needle is compatible for use with standard luer-slip and luer-lock syringes.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FDA

Digitally signed by Richard C. Chapman -S
Date: 2014.07.22 09:51:51 -04'00'

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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