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Section 17 - Summary of Safety and Effectiveness

17.1 Sponsor Name
Medical Technologies of Georgia, Inc.

JUL 17 2008

17.2 Device Name
MTG Instant Cath™
MTG Instant Cath™ Deluxe

17.3 Identification of Predicate or Legally Marketed Device
Apogee Closed System Catheter K032710

17.4 Device Description
The MTG Instant Cath™ is a sterile, closed system, single use, disposable, pre-lubricated PVC or Red Rubber (based on user preference for softness both are offered) catheter self-contained in a collection bag. It is used to drain urine from the bladder. When it is not practical or feasible for the patient to drain the bladder into a commode or bedpan, the urine may be drained into the collection bag. The MTG Instant Cath™ is designed with a collection bag and introducer tip for inserting the catheter without having to directly touch the catheter, reducing the possibility of contamination. The MTG Instant Cath™ Deluxe is the same as the MTG Instant Cath™, and includes an easy advancer that will make it less likely for the catheter to slip back into the bag during insertion. The purpose of this easy advancer, which does not come in contact with the patient, is solely to make the device easier for the patient or caregiver to advance the catheter and will in no way affect safety or effectiveness of the device. The MTG Instant Cath™ kit and MTG Instant Cath™ Deluxe kit include the intermittent catheter, with either PVP swabs and/or BZK prep pad/swab, gloves, gauze and an underpad. These products will be available in various sizes to accommodate a wide range of male, female and pediatric users.

17.5 Intended Use
MTG Instant Cath™, MTG Instant Cath™ kit,, MTG Instant Cath™ Deluxe and MTG Instant Cath™ Deluxe kit are intended to be used to drain urine from the patient's bladder.

17.6 Comparison of Technological Characteristics
The MTG Instant Cath™ kit and MTG Instant Cath™ Deluxe kit and the predicates have

1) the same intended use - Intermittent Catheterization; catheter inserted into bladder through urethra for emptying the bladder, typically not longer than 5 minutes per catheterization
2) same technologic characteristics - Pre-lubricated Polyvinylchloride (PVC) or Red Rubber catheter self-contained in a sterile collection bag with a silicone introducer tip and cap. Both are offered in a variety of sizes and kit component configurations

17.7 Performance Testing
The following performance tests were performed in comparison to the predicate:
Flow rate — all MTG devices were found to have a flow rate that equaled the predicate within +/- 10%. The MTG devices also all exceeded the specification criteria.

Lubricity – all samples of MTG Instant Cath™ and MTG Instant Cath™ Deluxe tested were determined to have exceeded the minimum quantity of gel for both the predicate and the specification criteria.

Catheter Tensile Strength - The tensile strength of the MTG Instant Cath™ and MTG Instant Cath™ Deluxe was evaluated in accordance with EN1616:1997 +A1:1999 "Sterile Urethral Catheters for Single Use" annex A "Test method for determining strength of catheter". All MTG Instant Cath™ and MTG Instant Cath™ Deluxe devices tested passed.

7.8- Statement of Equivalency

In Summary, the MTG Instant Cath™ and MTG Instant Cath™ Deluxe (including kits) have the same intended use as the Apogee Closed System Catheter and Apogee Closed System Catheterization Kit – cleared under 510(k) K032710 – Apogee Medical, Youngsville, NC. The functional performance test performed on both devices show equivalent performance capabilities.

The evaluation of the MTG Instant Cath™ and MTG Instant Cath™ Deluxe (including kits) does not raise any additional concerns regarding safety and effectivity and may therefore be considered substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2008

Ms. Cindi Sartain
President
Medical Technologies of Georgia, Inc.
15151 Prater Drive, Suite E
COVINGTON GA 30014

Re: K080878
Trade/Device Name: MTG Instant Cath™ and MTG Instant Cath™ Deluxe Catheter
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: KOD
Dated: July 7, 2008
Received: July 8, 2008

Dear Ms. Sartain:

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 (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. 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.

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); 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.

In addition, we have determined that your device kit contains Iodophor PVP Swabsticks which are subject to regulation as a drug.

Our substantially equivalent determination does not apply to the drug component of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component. For information on applicable Agency requirements for marketing this drug, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation, please contact the Office of Compliance at (240) 276-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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 (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4 - Indications for Use

0(k) Number (if known): K080878

Device Name:
MTG Instant Cath™
MTG Instant Cath™ kit with gloves, underpad, gauze, PVP swabsticks (3)
MTG Instant Cath™ kit with gloves, underpad, gauze, BZK prep pad/swab
MTG Instant Cath™ Deluxe
MTG Instant Cath™ Deluxe kit with gloves, underpad, gauze, PVP swabsticks (3)
MTG Instant Cath™ Deluxe kit with gloves, underpad, gauze, BZK prep pad/swab

Indications For Use:
~~MTG Instant Cath™, MTG Instant Cath™ kit (PVP or BZK), MTG Instant Cath™ Deluxe and MTG Instant~~ Cath™ Deluxe kit (PVP or BZK) are intended to be used to drain urine from the patient's bladder.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K080978