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Hakki Medical Technologies, Inc.
3851 62nd Avenue North, Suite A, Pinellas Park, Florida 33781

FEB - 7 · 2011

510(k) Summary

Submitted By:

Hakki Medical Technologies, Inc.
3851 62nd Avenue North
Pinellas Park, Florida 33781

Contact Persons:

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Date of Preparation: 14 September, 2010

Device:

Proprietary name - Hakki Urinary Catheter
Common name - Urinary catheter or Foley catheter
Classification name – Urological catheter (21 CFR 876.5130)
Product Class – Class II
Product Code – EZL

Predicate Devices:

The Hakki Urinary Catheter is substantially equivalent with respect to the following predicate devices: the Bard Malecot and Pezzer drains device (510(k) No. K070879) in terms of design, and the Bard Bardex® I.C. Latex Foley Catheter (510(k) No. K040658) in intended use.

Intended use:

The Hakki Urinary Catheter is used for continuous drainage of fluid to and from the urethra. Urinary tract access is generally accomplished by insertion of the catheter through the urethra and into the bladder. It must be connected to a standard urinary collector.

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Device Description:

The Hakki Urinary Catheter is used for continuous drainage of fluid to and from the urethra and is an improved version of the straight urinary catheter. The Hakki catheter has built-in expandable/retractable Malecot type wings permitting holding capabilities less than that of a Foley catheter, but allows greater holding power than a straight catheter. By design the Hakki catheter has the ability to maximize drainage of a bladder, due to the location of its drainage opening at the natural drainage point within the bladder. The Hakki catheter is activated by expanding and contracting the catheter through the built-in patented bellows, which open and close the wing tip. The newly designed Hakki urinary catheter functions in the same manner as a straight or Foley catheter and is inserted through the urethra into the bladder.

Substantial Equivalence:

The Hakki Urinary Catheter is comparable with respect to intended use to the published predicate device description and meets the requirements for 510(k) substantial equivalence.

Test Data:

Non-clinical device performance testing such as flow rate, expanded leaflet integrity, & response to pullout were evaluated. Testing was performed in accordance to Food and Drug Administration guidance's and recognized international standard ASTM F 623-99 (Reapproved 2006). Results of these tests showed substantial equivalence with international standard ASTM F 623-99 (Reapproved 2006).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Andrew Endahl
Plant Manager
Hakki Medical Technologies, Inc.
3851 62nd Avenue, North, Suite A
PINELLAS PARK FL 33781

FEB - 7 2011

Re: K101900
Trade/Device Name: Hakki Urinary Catheter
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: GBM
Dated: January 5, 2011
Received: January 6, 2011

Dear Mr. Endahl:

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,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101900

Indications for Use

510 (k) Number (if known)

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Device Name: Hakki Urinary Catheter

Indications for Use:

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Prescription Use: X and/or Over-the Counter Use: ____

(Part 21 CFR 801) (21 CFR 807)

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

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K101900