K092827

dimeda
SURGICAL INSTRUMENTS

JAN - 8 2010

>> 510(k) Summary

Date: 1/7/2010

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Trade name: Dimeda Obstetrical Forceps / K092827

Common name: Obstetrical forceps

Classfication name: Obstetric forceps (21 CFR 884.4400, Product code HDA)

Substantial Equivalence Obstetrical forceps:
K013747 - Tekno-Medical Obstetrical Forceps / K951529 - V. MUELLER Obstetrical (OB) Forceps

Description of the Device:

The Dimeda Obstetrical Forceps is a surgical medical device for medical procedure to grasp the fetal head when it is in the vagina and bring about delivery by traction and guidance without causing injury to the mother or baby. The forceps consists of two arms which are movable. The device is manufactured from surgical stainless steel.
The Dimeda Obstetrical Forceps should only be used in settings in which personnel are readily

available to perform casarean delivery in the event that operative delivery is unsuccessful. Obstetrical forceps should not be used by individuals who are not fully trained in the proper use of forceps and the potential complications associated with their use.

The common names of obstetrical forceps included in this submission: Wrigley, Simpson, Simpson Braun, De Lee, Elliot, Naegele, Luikart, Simpson Luikart, McLean Tucker Luikart, McLean Tucker, McLean Luikart, McLean, Boerma, Dewey, Tarnier, Bill, and Luikart Bill.

Indications for Use:

The Dimeda Obstetrical Forceps are intended to grasp and apply traction to the fetal head to facilitate vaginal delivery, provided that the cervix is fully dilated and the fetal head is positioned appropriately in the vagina. Use of the forceps is indicated for:

- prolonged second stage
- suspicion of immediate or potential fetal compromise
- shortening of the second stage for maternal benefit

Comparison with predicate devices:

The Dimeda Obstetrical Forceps are identical in intended use, indications for use, target population, hospital use, material, design, biocompatibility, sterilization method, performance, mechanical safety characteristics and partly in terms of sizes to the Tekno-Medical Obstetrical Forceps (K013747) and V. MUELLER Obstetrical (OB) Forceps (K951529). There are mainly no differences of the Dimeda Obstetrical Forceps to the predicate devices.
By the Dimeda Obstetrical Forceps have been no modification made (regarding to design, method of operation, mechanical performance), hence it's safety and effectiveness haven't been affected compared to the predicate devices.

Therefore the Dimeda product can be deemed substantially equivalent and safe and effective for its indicated use.

Summary:

The presented data that was conducted on the Dimeda Obstetrical Forceps shows in its results and in comparison to the predicate devices that the products are absolutely safe and effective for their intended use and do not raise any questions regarding safety and effectiveness. All models that are covered by this 510(k) premarket notification have been on the market in Europe for many years with no device failures. The used materials are well researched and do not raise new questions regarding safety and effectiveness of the finished product.

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

Dimeda Instrumente GmbH
% Ms. Andrea Pecsi
Regulatory Affairs Specialist
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JAN – 8 2010

Re: K092827
Trade/Name: Dimeda Obstetrical Forceps
Regulation Number: 21 CFR §884.4400
Regulation Name: Obstetric forceps
Regulatory Class: II
Product Code: HDA
Dated: November 25, 2009
Received: November 30, 2009

Dear Ms. Pecsi:

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.

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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K092827

Device Name:
Dimeda Obstetrical Forceps

Indications for Use:

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- o shortening of the second stage for maternal benefit

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K092827