510(k) Summary

510(k) Summary as required by section 807.92(c) **K100517**

APR 29 2010

date prepared 04/26/2010

Submission Applicant:

INSTRUMED INTERNATIONAL, INC.
626 Cooper Court
Schaumburg, IL 60173

Establishment Registration Number:

1421101

Official Correspondent:

Mr. Berndt Fetzer
INSTRUMED INTERNATIONAL, INC.
626 Cooper Court
Schaumburg, IL 60173

Phone: 847-908-0292

Trade name:
Instrumed Obstetrical Forceps

Common name:
Various Obstetric-Gynaecologic specialized manual instruments/Obstetrical Forceps:

Simpson, Wrigley, Elliott, De Lee, Luikart Simpson, Piper, McLean-Luikart, Mclean-Tucker-Luikart, Boerma, Naegele

Classification name:

21 CFR PART 884 -- OBSTETRICAL AND GYNECOLOGICAL DEVICES
Subpart E--Obstetrical and Gynecological Surgical Devices

Sec. 884.4400 Obstetric forceps. Product Code HDA

Regulation Description

Obstetric-gynecologic specialized manual instrument/forceps

Substantial Equivalence Claims:

HDA

K013747 TEKNO-MEDICAL OBSTETRICAL FORCEPS
Applicant TEKNO MEDICAL OPTIK-CHIRURGIE GMBH & CO.

K951529 V. MUELLER OBSTETRICAL (OB) FORCEPS
Applicant BAXTER HEALTHCARE CORP.

510(k) Summary

Description of the Device:

Instrumed obstetrical forceps are instruments designed to aid in the delivery of the fetus.
Many different types of forceps have been described and developed. Generally, forceps consist of 2 mirror image metal instruments that are manoeuvred to cradle the fetal head and are articulated, after which traction is applied to effect delivery.

Forceps have 4 major components, as follows:

- Blades: The blades grasp the fetus. Each blade has a curve to fit around the fetal head. The blades are oval or elliptical and can be fenestrated (with a hole in the middle) or solid. Many blades are also curved in a plane 90° from the cephalic curve to fit the maternal pelvis (pelvic curve).
- Shanks: The shanks connect the blades to the handles and provide the length of the device. They are either parallel or crossing.
- Lock: The lock is the articulation between the shanks. Many different types have been designed.
- Handles: The handles are where the operator holds the device and applies traction to the fetal head.

The surgeon chooses the obstetrical/gynaecological forceps based on the anatomy of the site and the type desired, based on the type of the surgical procedure.

Instrumed obstetrical forceps are made of the ASTM F 899-09 standardized Stainless Steel.
The instruments are offered in non-sterile condition.

Indications for Use:

INSTRUMED Obstetrical Forceps are intended to grasp and apply traction to the fetal head to facilitate delivery for the following indications, provided that the fetal head is positioned appropriately in the vagina:

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

Comparison with Predicate Device:

The results of non-clinical and bench testing indicates that the new device is completely comparable to the predicate devices. Biocompatibility and sterilization studies were successfully completed.

The Instrumed product is similiar to the predicate device in terms of technical characteristics, design, Indications for Use, Target population, where it is used, performance, biocompatibility, sterilisation method, mechanical safety characteristics as well as sizes and configurations. **Therefore it can be deemed substantially equivalent and safe and effective for its indicated use.**

Summary

The presented data that was conducted on the Instrumed Instruments 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 new questions regarding safety and effectiveness. 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

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

Mr. Michael Massong
RA/QA Director
Instrumed International, Inc.
626 Cooper Court
SCHAUMBURG IL 60173

APR 29 2010

Re: K100517
Trade/Device Name: Instrumed Obstetrical Forceps
Regulation Number: 21 CFR §884.4400
Regulation Name: Obstetric forceps
Regulatory Class: II
Product Code: HDA
Dated: February 16, 2010
Received: February 23, 2010

Dear Mr. Massong:

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,

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

510(k) Number (if known): K100517

Device Name: Instrumed Obstetrical Forceps

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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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K100517