510(k) SUMMARY

JAN 17 2014

1. Date: January 9, 2014

2. Submitter:
IOB Medical Inc
504E Diamond Ave., Suite F
Gaithersburg, MD 20877

3. Contact person:
Joe Shia
IOB Medical Inc.
504 East Diamond Ave., Suite F
Gaithersburg, MD 20878
Telephone: 301-250-0831
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4. Device Name: IOB Disposable Speculum

5. Classification:
ClassII

Product Code	CFR #	Panel
HIB	21CFR 884-4530 Speculum Vaginal nonmetal	OBSTRETICS AND GYNECOLOGY

6. Predicate Devices:
K091937
OBP Office-Spec Disposable Side Speculum

7. Intended Use
The IOB Disposable Speculum is used to dilate the vagina and expose the interior of the vagina and the exterior of the cervix during pelvic examinations and other gynecologic procedures. It may be used with or without a removable light source.

8. Device Description
The IOB disposable vaginal speculum consists of up and under plastic blades and handle with three different sizes (small, medium and large). The speculum is used by medical professionals to visualize interior of vagina and cervix during patient examination.

9. Technological Characteristics
The IOB disposable vaginal speculum has the same technological characteristics and indications for use as the predicate device. The new device is constructed using polystyrene that is commonly used by the medical device industry for like and similar devices. The device was tested for biocompatibility per FDA General Program Memorandum G95-1 and ISO 10993-1 requirements for limited contact duration, and was found to be compatible for the intended use of the product.

10. Substantial Equivalence Information

A summary comparison of features of the IOB Disposable Speculum and the predicate devices is provided in Table 1

Table 1: Features Comparison of the IOB Disposable Speculum and the Predicate Device

Item	Device	Predicate – K091937
Intended Use	For use on women undergoing a procedure requiring vaginal access and exposure. For prescription use.	Same
Material	PS	Same
Performance	Hand held and manually operated, multi-position, clear viewing	Same
Configuration	Bi-valve plastic blades	Same
Usage	single use	Same
Sterility	Non-sterile	Same
Assembly	No assembly required	Same
Differences		
Item	**Device**	**Predicate – K091937**
Packaging	20 small or medium size per pack 18 large size per pack	18 small or medium size per pack 16 large size per pack

11. Safety and Performance Characteristics

1. Biocompatibility testing (cytotoxicity, irritation and sensitivity) according to ISO 10993 for a limited contact device was demonstrated to be suitable for the intended use of the product.
2. Bench Testing and Stability Studies

   Bench testing was performed by simulating actual usage comparing the device with the predicate speculum. The testing results show that the new device performs equivalent to the predicate device. Both bench testing and stability study show that the device is able to survive stresses encountered during use without failure.

12. Conclusion

Based on the information presented in this 510K premarket notification, the IOB Disposable Speculum is substantially equivalent to the predicate.

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

January 17, 2014

IOB Medical, Inc.
Joe Shia
Regulatory Affairs
504 East Diamond Avenue, Suite F
Gaithersburg, MD 20877

Re: K132668
Trade/Device Name: IOB Disposable Speculum
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: HIB
Dated: November 29, 2013
Received: December 4, 2013

Dear Joe Shia,

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 -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K132668

Device Name: IOB Disposable Speculum

Indications for Use:

The IOB Disposable Speculum is used to dilate the vagina and expose the interior of the vagina and the exterior of the cervix during pelvic examinations and other gynecologic procedures. It may be used with or without a removable light source.

Prescription Use __X__ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Herbert P. Lerner -S
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Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

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