DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 5, 2014

EIS Corporation
% Ho Dong, Yang
CEO
Onbix Corporation
#821 Samil Plaza
837-26 Yeuksam-dong,
Gangnam-gu (135-768), Seoul Korea

Re: K132313
Trade/Device Name: Pessary
Regulation Number: 21 CFR 884.3575
Regulation Name: Vaginal Pessary
Regulatory Class: Class II
Product Code: HHW
Dated: October 31, 2014
Received: November 6, 2014

Dear Ho Dong, Yang

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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 Form

510(k) Number (if known): ____K132313_____

Device Name: Pessary

Indications for Use:

EIS Vaginal Pessaries are indicated for the use as removable structures placed in the vagina to treat uterine prolapse, including cystocele and rectocele, as well as stress urinary incontinence in women

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

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Division Sign-Off
Office of Device Evaluation

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Submitter Information:
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Date Summary Prepared: Nov 24, 2014

Device Name:

Trade Name(s):	Pessary
Classification Name:	Vaginal pessary
Panel:	Obstetrics/Gynecology
Product code:	HHW
Regulation:	21 CFR 884.3575

Predicate Device Information:
K092981 / PANPAC VAGINAL PESSARY (Panpac Medical Corporation)

Device Description:
The subject device is a silicone vaginal pessary. The submission includes the following designs: cube, dish, donut, marland, oval, gellhorn, gellhorn short, shaatz, and ring.

Intended Use:
EIS Vaginal Pessaries are indicated for the use as removable structures placed in the vagina to treat uterine prolapse, including cystocele and rectocele, as well as stress urinary incontinence in women.

Comparison to Predicate Device(s):
This subject device is equivalent to the predicate device in its intended use and technological characteristics. The following table compares the technological characteristics of the subject and predicate device.

No	Item	Pessary (new device, K132313)	PANPAC VAGINAL PESSARY (K092981)
1	Manufacturer	EIS Corporation	Panpac Medical Corporation
2	Material	silicone	Silicone
3	Shape	Various and similar	Various and similar
4	Size	Various and similar	Various and similar
5	Class	Class 2	Class 2
6	Indications for use	Effective support for cystocele, rectocele, uterine prolapsed or procidentia, urinary incontinence	Effective support for cystocele, rectocele, uterine prolapsed or procidentia, urinary incontinence

Non-Clinical Study performance

The performance testing provided included shelf life and biocompatibility testing per ISO 10993-1. The completed biocompatibility tests included the following:

Cytotoxicity
Intracutaneous (intradermal) reactivity
Skin sensitization
Acute systemic toxicity

Conclusion
Based on the information provided in this summary we conclude that pessary is substantially equivalent to the predicate device K092981 (PANPAC VAGINAL PESSARY - Panpac Medical Corporation).