DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 19, 2014

Gynetech Pty. Ltd.
% Kevin MacDonald
Clinical/Regulatory Consultant
229 Marvilla Circle
Pacifica, CA 94044

Re: K142700
Trade/Device Name: InsufflatOR Needle, 12cm/15cm
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic insufflator
Regulatory Class: II
Product Code: HIF
Dated: November 16, 2014
Received: November 21, 2014

Dear Kevin MacDonald,

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

Section 6: Indications for Use Statement

Indications for Use

510(k) Number (if known): K142700

Device Name: InsufflatOR Needle

Indications for Use:

The InsufflatOR Needle™ is intended for percutaneous insertion into the peritoneal cavity for the purpose of insufflation with carbon dioxide, to establish pneumoperitoneum prior to the placement of trocars during laparoscopic procedures.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Section 7: 510(k) Summary

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

Submitted by:	Gynetech Pty Ltd 122-124 Balmain Street, Richmond VIC 3121, Australia Phone: +61 3 9413 5555 Contact email: qa@gynetech.com.au Fax: +61 3 9413 5555
Contact Person	Kevin MacDonald Clinical/Regulatory Consultant 229 Marvilla Circle Pacifica, CA 94044 Phone: 415-609-9875 Email: k-macdonald@sbcglobal.net
Date Prepared:	December 17, 2014
Proprietary Name:	InsufflatOR Needle
Common Name:	Veress Needle
Classification:	II
Regulation Number:	884.1730
Regulation Name:	Laparoscopic insufflator
Panel:	Obstetrics/Gynecology
Product Code:	HIF
Predicate Devices:	GeniCon Pneumo-Needle (K993625)
Device Description:	The Gynetech InsufflatOR Needle is a sterile disposable Veress needle which is available in 120mm or 150mm length. The device is equipped with a spring-loaded, round-tipped obturator. In addition, there is a “slide switch” which permits easy ON-OFF control of gas flow. The most proximal end contains a male luer lock connector for connection to a CO_2 gas line. The InsufflatOR Needle has applications in gynaecological laparoscopy and other laparoscopic procedures.
Indications for Use:	The InsufflatOR Needle™ is intended for percutaneous insertion into the peritoneal cavity for the purpose of insufflation with carbon dioxide, to establish pneumoperitoneum prior to the placement of trocars during laparoscopic procedures.

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Comparison of Subject Device to Predicate Device		
Attribute	**InsufflatOR Needle**	**GeniCon Pneumo-Needle**
510(k) number	K142700	K993625
Regulation Number	884.1730	884.1730
Classification	Class II	Class II
Classification Name	Insufflator, Laparoscopic	Insufflator, Laparoscopic
Product Code and Classification Panel	HIF Obstetrics/Gynecology Panel	HIF Obstetrics/Gynecology Panel
Manufacturer	Advanced Medical Design International LLC (see Establishment Registration Details in Attachment 5)	Same
Description	The Gynetech InsufflatOR Needle is a sterile and single use product. It incorporates a spring loaded blunt style mechanism. It is used to establish pneumoperitoneum prior to trocar and cannula insertion during laparoscopic procedures. The InsufflatOR Needle is available in 120mm and 150mm lengths and has applications in gynaecological laparoscopy and other laparoscopic procedures.	The GeniCon Pneumo-Needle is a sterile disposable Veress needle which is available in 120mm or 150mm length. The device is equipped with a spring-loaded, round-tipped obturator. In addition, there is a “slide switch” which permits easy ON-OFF control of gas flow. The most proximal end contains a male luer lock connector for connection to a CO2 gas line.
Indications for Use	The InsuffaltOR Needle™ is intended for percutaneous insertion into the peritoneal cavity for the purpose of insufflation with carbon dioxide, to establish pneumoperitoneum prior to the placement of trocars during laparoscopic procedures.	Same
Anatomical sites	Abdominal	Same
Consisted Instruments	Veress Needle Obturator	Same
Materials	Hub - Model grade PC Gas Trap – High density Polyethylene (HDPE)	Same

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Comparison of Subject Device to Predicate Device		
Attribute	**InsufflatOR Needle**	**GeniCon Pneumo-Needle**
	Shaft - Stainless Steel 304 (Inner shaft 1.6*135 / Outer shaft 2.1*131) Spring - Stainless steel and ABS pink	
Dimensions	Length: 120mm or 150mm	Same
Performance Standards	Not Applicable	Not Applicable
Sterilization method	Ethylene Oxide	Gamma radiation
Packaging	Tyvek pouch	Same

Performance Data
The contract manufacturer, Advanced Medical Design International, LLC, manufactures the InsufflatOR Needle to the same exact specifications as the predicate device by GeniCon. This includes specifications for: • Tip pull test • Switch operation test • Spring obturator test • Needle puncture force test To evaluate the change in sterilization method, the following tests were conducted on the InsufflatOR Needle: • EtO Sterilization Validation in accordance with ISO 11135-1:2007 Sterilisation of Healthcare Products – Ethylene Oxide • Ethylene Oxide Sterilisation Residuals, ISO 10993-7:2008 Biological Evaluation of Medical Devices • Packaging integrity and device functional performance testing following accelerated aging.

Conclusion:

All testing undertaken to demonstrate substantial equivalence of the Gynetech InsufflatOR Needle meets the requirements of its predetermined acceptance criteria and intended use. The acceptance criteria and intended use of the Gynetech InsufflatOR Needle are identical to the predicate device. These test results confirm that the Gynetech InsufflatOR Needle is as safe and effective as the predicate device.