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

August 26, 2016

Fortimedix Surgical B.V.
% Mr. Richard Vincins
Vice President, QA/RA
Emergo Global Consulting, LLC
816 Congress Avenue
Suite 1400
Austin, Texas 78701

Re: K160797
Trade/Device Name: FMX314 Surgical Platform
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OTJ, GCJ
Dated: August 3, 2016
Received: August 9, 2016

Dear Mr. Vincins:

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,

Christopher J. Ronk -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160797

Device Name
FMX314 Surgical Platform

Indications for Use *(Describe)*
The FMX314 Surgical Platform is composed of FMX314 Introducer and FMX314 Instruments that are used in minimally invasive abdominal laparoscopic surgery:

- The FMX314 Introducer is intended to establish a path of entry for laparoscopic instruments for use during minimally invasive abdominal laparoscopic surgery in combination with the FMX314 Instruments.

- The FMX314 Instruments are intended for use in minimally invasive abdominal laparoscopic surgical procedures for grasping, mobilizing, dissecting, retracting, cutting, cauterizing, ligating, and suction irrigation of tissues and vessels during laparoscopic procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

FMX314 Surgical Platform

K160797

1. Submission Sponsor

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3. Date Prepared

24 August 2016

4. Device Identification

Trade/Proprietary Name:	FMX314 Surgical Platform
Common/Usual Name:	General and Plastic Surgery Laparoscope
Classification Name:	Endoscope and Accessories
Regulation Number:	876.1500
Product Code:	GCJ, OTJ
Device Class:	Class II

Classification Panel: General & Plastic Surgery

5. Legally Marketed Predicate Device(s)

K090902, SPIDER™ Single Port Surgical Device, TransEnterix, Inc.

K091697, SPIDER™ Surgical Instruments, TransEnterix, Inc.

6. Device Description

The FMX314 Surgical Platform is a single-port laparoscopic surgery platform, featuring single-use, disposable articulating surgical instruments for the purpose of doing minimally invasive abdominal laparoscopic surgery by closely mimicking multi-port laparoscopic surgery. The FMX314 Surgical Platform is composed of the reusable FMX314 Introducer, the single-use FMX314 Hub Cap & Sealing Unit, and the single-use FMX314 Instruments that are used as part of laparoscopic surgery according to the intended use. The FMX314 Surgical Platform does not require a larger diameter incision than standard laparoscopic surgery (compatible with a single, standard 15mm trocar) and will utilize currently marketed conventional 15mm laparoscopic access devices (trocars), rigid 5mm laparoscopes, and instrument compatible handles for instrument manipulation and monopolar cutting and cauterizing.

The FMX314 Introducer is a reusable, single port access device for abdominal laparoscopic surgical procedures to be used in combination with a standard 15 mm trocar, FMX314 Hub Cap & Sealing Unit assembly (accessory), and the FMX314 Instruments. The FMX314 Introducer is designed for introducing, holding, supporting and guiding the FMX314 Instruments and a standard, rigid 5 mm laparoscope. The cavity at the top of the FMX314 Introducer (hub) is designed to place the single-use FMX314 Hub Cap & Sealing Unit. The FMX314 Hub Cap & Sealing Unit is designed to maintain pneumoperitoneum in the abdomen during the surgical procedure, whether or not one or more FMX314 Instruments are inserted in the instrument lumen(s) of the Introducer. Locking recesses in the hub guide the correct placement of the FMX314 Sealing Unit. The bayonet fitting at the outside of the hub is designed to properly position the single-use FMX314 Hub Cap & Sealing Unit on the FMX314 Introducer and to lock the FMX314 Sealing Unit in the hub. By turning the FMX314 Hub Cap clockwise a “click” is heard indicating that the FMX314 Hub Cap & Sealing Unit is locked into position. Prior to its reuse after completion of a procedure the FMX314 Introducer has to be disassembled, cleaned, reassembled and sterilized per Instructions For Use.

The FMX314 Surgical Platform comprises six (6) disposable articulating laparoscopic surgical instruments (i.e. FMX314 Grasper, Maryland, Clip Applier, Scissors, Hook-knife, and Suction/Irrigation Instrument). The FMX314 Instruments are locked into position in the instrument clamps of the FMX314 Introducer to activate a triangulated approach within the surgical field and facilitate independent anterior/posterior mobility. Each instrument is capable of 360 degree axial rotation of the end-effector as well as multi-directional lateral and superior/inferior mobility.

The FMX314 Instruments and FMX314 Hub Cap & Sealing Unit are provided sterile and are single-use, disposable. When the surgical procedure is completed, the single-use FMX314 Instruments as well as the FMX314 Hub Cap & Sealing Unit are removed from the Introducer and discarded according to standard hospital protocol.

7. Indication for Use Statement

The FMX314 Surgical Platform is composed of FMX314 Introducer and FMX314 Instruments that are used in minimally invasive abdominal laparoscopic surgery:

- The FMX314 Introducer is intended to establish a path of entry for laparoscopic instruments for use during minimally invasive abdominal laparoscopic surgery in combination with the FMX314 Instruments.
- The FMX314 Instruments are intended for use in minimally invasive abdominal laparoscopic surgical procedures for grasping, mobilizing, dissecting, retracting, cutting, cauterizing, ligating and suction-irrigation of tissues and vessels during laparoscopic procedures.

8. Substantial Equivalence Discussion

The following table compares the FMX314 Surgical Platform (FMX314 Introducer and FMX314 Instruments) to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table 5A – Comparison of Characteristics – FMX314 Introducer

Manufacturer	**Fortimedix Surgical B.V.**	**TransEnterix, Inc.**	**Significant Differences**
Trade Name	**FMX314 Surgical Platform (FMX314 Introducer)**	**SPIDER™ Single Port Surgical Device**	
510(k) Number	K160797	K090902	N/A
Product Code	OTJ	GCJ	Different; the FDA advised that Product Code OTJ is used for the FMX314 Introducer
Regulation Number	876.1500	876.1500	Same
Regulation Name	Laparoscopic Single Port Access Device	General and Plastic Surgery Laparoscope	N/A
Indications for Use	The FMX314 Introducer is intended to establish a path of entry for laparoscopic instruments for use during minimally invasive abdominal laparoscopic surgery in combination with the FMX314 Instruments.	The SPIDER™ (Single Port Instrument Delivery Extended Reach) is intended to establish a path of entry for laparoscopic instruments for use during minimally invasive abdominal laparoscopic surgery.	Same

Manufacturer	Fortimedix Surgical B.V.	TransEnterix, Inc.	Significant Differences
Trade Name	**FMX314 Surgical Platform (FMX314 Introducer)**	**SPIDER™ Single Port Surgical Device**	
Overview of Design, Principles of Operation	The FMX314 Surgical Platform consists of: - the FMX314 Introducer, - the FMX314 Hub Cap & Sealing Unit - five (5) semi-flexible, double-articulating FMX314 Instruments (Grasper, Scissors, Maryland, Clip-Applier and Hook-knife) and - one (1) semi-flexible, single-articulating FMX314 Suction/Irrigation Instrument The FMX314 Introducer is a rigid, reusable single port delivery system with four (4) lumens to facilitate multi-instrument access. The superior lumen is designated for a 5mm rigid laparoscope; the two lateral ports are designated for the instruments and the inferior lumen for the suction/irrigation. The FMX314 Introducer is inserted into a standard 15 mm Trocar after insufflation of the abdomen. It includes a fume release port for smoke evacuation. The FMX314 Instruments get steered and activated with handles with a rotating knob. The FMX314 Surgical Platform allows for x, y, and z as well as rotational motion for a multidirectional approach of the surgical field, mimicking the	The single use SPIDER™ device consists of: - the SPIDER™ Single Port Surgical Device - the SPIDER™ Surgical Instruments (flexible and rigid) The SPIDER™ Single Port Surgical Device is a rigid, pre-sterilized introducer with four channels. Two of the channels known as IDTs (Instrument Delivery Tubes) are positioned left and right and include extended lumens to facilitate manipulation of flexible surgical instruments, enabling control of the instruments over extended distances. These 2 IDTs are flexible and allow for x, y, and z motion for a multidirectional approach of the surgical field, mimicking the approach of standard laparoscopic surgery using pistol grip handles with a rotating knob on the flexible surgical instruments. Two (2) rigid channels, north to south, can accommodate an endoscope or a rigid surgical instrument. The SPIDER™ Single Port Surgical Device includes ports for insufflation or smoke evacuation.	Similar; both platforms are single access platforms, and allow for motion of laparoscopic Instruments for a multidirectional approach of the surgical field. Both platforms have a port for smoke evacuation. The SPIDER™ Single Port Surgical Device is for single-use only and requires a bigger incision because of its larger outer diameter compared to the reusable FMX314 Introducer. Furthermore, the flexible SPIDER™ Surgical Instruments do not have inherent stiffness and get steered and activated via the Instrument Delivery Tubes, while the FMX314 Instruments are semi-flexible and activated and articulated via the instrument handle. The differences in the overall design and the principle of operation and use of the FMX314 Surgical Platform are minor and do not raise any additional questions of safety or efficacy as the general principle for use of the device is the same and is used in the same surgical procedures.

Manufacturer	Fortimedix Surgical B.V.	TransEnterix, Inc.	Significant Differences
Trade Name	**FMX314 Surgical Platform (FMX314 Introducer)**	**SPIDER™ Single Port Surgical Device**	
	approach of standard laparoscopic surgery.		
Materials – Introducer	Introducer body: Stainless steel 316L and PEEK Instrument Clamps & Axial Guiding: Aluminum AL 6082 Bearings: PTFE Rulon 641 Spring: Stainless steel 301	Stainless steel and Plastic materials	Similar; the materials composing the introducer component are common materials that are used in other medical devices. The materials do not introduce any concerns for safety and efficacy as the performance testing of the FMX314 Surgical Platform assures proper functioning.
Materials – Hub Cap & Sealing Unit	FMX314 Hub Cap: PEEK FMX314 Sealing Unit: Silicone rubber, PBT	Plastic materials	Similar; the materials composing the FMX314 Hub Cap & Sealing Unit are common materials that are used in other medical devices. These materials do not introduce any concerns for safety and efficacy as the performance testing of the FMX314 Sealing Unit assures proper functioning.
Number of Lumens	4	4	Same
Stationary Lumens	4	2	Similar; the FMX314 Introducer provides stationary lumens only, this does not introduce any new safety or efficacy concerns as compared to the predicate device.
Flexible Lumens	0	2	Different; the FMX314 Introducer provides stationary lumens only for robust lumen pathway that does not introduce any new safety or efficacy concerns as compared to the predicate device.

Manufacturer	Fortimedix Surgical B.V.	TransEnterix, Inc.	Significant Differences
Trade Name	**FMX314 Surgical Platform (FMX314 Introducer)**	**SPIDER™ Single Port Surgical Device**	
Degrees of Rotation	360° of independent movement of instruments at distal end	360° of independent movement of instruments at distal end	Same
Lumen Diameter	3 x 6 mm (lateral, superior) 1 x 3.6 mm (inferior)	2 x 7.2 mm (flexible) 2 x 6 mm (stationary)	Similar; the semi-flexible FMX314 Instruments have a smaller diameter; these do not introduce any new concerns of safety and efficacy as the lumen diameter accommodates the instruments for each platform.
Overall Length	27.5 cm (with fully engaged axial guidance; extreme posterior position) 34.0 cm (with fully extended axial guidance; extreme anterior position)	72 cm	Different; the FMX314 Instruments are semi-flexible and have an inherent stiffness through the material composition. Thus the instruments do not need full support along the length. The smaller length of the introducer does not introduce any additional concerns for safety or efficacy.
Outer Diameter (Shaft)	15.5 mm	18.9 mm (without plastic tube)	Similar; the SPIDER™ Single Port Surgical Device has a 3.4 mm larger diameter; as the path of entry is smaller than the predicate device, this does not introduce any new concerns for safety and efficacy.
Sterile	Introducer: Supplied non-sterile; user sterilized Hub Cap & Sealing Unit: Supplied sterile, single-use only	Supplied sterile, single-use only	Different; the entire predicate device is single-use only compared to reusability of the FMX314 Introducer. Reprocessing validation and lifecycle verification supports no new concerns for safety or efficacy introduced.

Manufacturer	Fortimedix Surgical B.V.	TransEnterix, Inc.	Significant Differences
Trade Name	**FMX314 Surgical Platform (FMX314 Introducer)**	**SPIDER™ Single Port Surgical Device**	
Single-Use	The Introducer is reprocessed according to instructions Hub Cap & Sealing Unit: Single-use only, disposed of after use	Single-use only	Different; the entire predicate device is single-use only compared to reusability of the FMX314 Introducer. Reprocessing validation and lifecycle verification supports no new concerns for safety or efficacy introduced.
Packaging	Holding tray in a carton box	Holding tray in a carton box	Same
Shelf Life	Introducer: 5 years Hub Cap & Sealing Unit: 2 years	Not known	N/A

Table 5B – Comparison of Characteristics – FMX314 Instruments

Manufacturer	Fortimedix Surgical B.V.	TransEnterix, Inc.	Significant Differences
Trade Name	**FMX314 Surgical Platform (FMX314 Instruments)**	**SPIDER™ Surgical Instruments**	
510(k) Number	K160797	K091697	N/A
Product Code	GCJ	GCJ	Same
Regulation Number	876.1500	876.1500	Same
Regulation Name	General and Plastic Surgery Laparoscope	General and Plastic Surgery Laparoscope	Same
Indications for Use	The FMX314 Instruments are intended for use in minimally invasive abdominal laparoscopic surgical procedures for grasping, mobilizing, dissecting, retracting, cutting, cauterizing, ligating and suction irrigation of tissues and vessels during laparoscopic procedures.	The SPIDER Surgical Instruments are intended for use in minimally invasive abdominal laparoscopic surgical procedures for grasping, mobilizing, dissecting, retracting, cutting, cauterizing, ligating, suction irrigation, and other manipulation of tissues and vessels during laparoscopic procedures.	Similar; the phrase 'and other manipulation' was removed from the indications as discussed with the FDA during a Q-Sub meeting.

Manufacturer	Fortimedix Surgical B.V.	TransEnterix, Inc.	Significant Differences
Trade Name	**FMX314 Surgical Platform (FMX314 Instruments)**	**SPIDER™ Surgical Instruments**	
Types of Instruments	FMX314 Grasper FMX314 Maryland FMX314 Scissors FMX314 Clip Applier FMX314 Hook-Knife FMX314 Suction-Irrigation	Fenestrated Grasper Maryland Dissector Flex Shears Clip Applier Monopolar Hook Suction Irrigator	Same
Design Configuration	Semi-flexible, articulating laparoscopic instrument made of telescoped tubes; pistol grip handle with rotating knob (except for the Hook-Knife and the Suction/Irrigation instruments)	Flexible laparoscopic instrument; pistol grip handle with rotating knob (except for the Hook-Knife and the Suction/Irrigation instruments)	Similar; compared to the flexible SPIDER™ Instruments which have no inherent stiffness and can only be manipulated within the flexible lumens of the SPIDER™ Single Port Surgical Device, the FMX314 Instruments are semi-flexible with an inherent stiffness. The use of the instruments are the same for the indications for use and surgical application that is supported by performance testing of the instruments which does not raise any new concerns for safety or efficacy.
Materials	Stainless steel tooltips; stainless steel tubing; polyolefin sheathing	Stainless steel tooltips; Sheathing material unknown	Similar; there is no difference in the tool-tip material as both are stainless steel. All patient contacting materials used with the FMX314 Instruments are biocompatible and do not introduce any new safety or efficacy concerns.
Length (Overall)	FMX314 Grasper: 63 cm (without handle) of which up to 33 cm is inside the abdominal cavity FMX314 Maryland: 63 cm	Fenestrated Grasper: About 84 cm (without handle) of which up to 34 cm is inside the abdominal cavity Maryland Dissector: About	Similar; the instruments of the predicate device need to fit through the SPIDER™ Introducer which has an overall length of 72cm;

Manufacturer	Fortimedix Surgical B.V.	TransEnterix, Inc.	Significant Differences
Trade Name	**FMX314 Surgical Platform (FMX314 Instruments)**	**SPIDER™ Surgical Instruments**	
	(without handle) FMX314 Scissors: 62 cm (without handle) FMX 314 Clip Applier: 63 cm (without handle) FMX314 Hook-knife: 59 cm (without handle); 73 cm (including handle) FMX314 Suction-Irrigation: 68 cm (without connector)	84 cm (without handle) Flex Shears: Unknown Clip Applier: Unknown Monopolar Hook: Unknown Suction – Irrigator: About 80 cm (without connector)	taking the bends of the flexible lumens of the SPIDER™ Single Port Surgical Device into account, the flexible SPIDER™ Instruments need to be longer than 72 cm. This does not introduce any safety or efficacy concerns as the manipulation of the instrument is the same and the operating principles is the same.
Length (Tooltip)	FMX314 Grasper: 36 mm FMX314 Maryland: 33 mm FMX314 Scissors: 26 mm FMX314 Clip Applier: 34 mm FMX314 Hook-knife: 14 mm	Fenestrated Grasper About 26 mm Maryland Dissector: About 25.5 mm Flex Shears: Unknown Clip Applier: Unknown Monopolar Hook: Unknown	Similar; the slightly longer tool-tip of the FMX314 Instrument does not introduce any new safety and efficacy concerns as this is only 1 cm which does not have a significant impact on use of the tool.
Shaft Diameter	5 mm	About 3.2 mm	Similar; the shaft diameter is slightly larger to accommodate the construction of the flexible instruments. This does not raise any additional safety or efficacy concerns as the instruments fit through the introducer lumens.
Sterile	Yes by gamma sterilization	Yes by EtO sterilization	Similar; these are both validated methods with the Sterility Assurance Level (SAL) of 10^{-6} so this does not introduce any new safety or efficacy concerns.
Electrical Safety Testing	Yes	Yes	Same
Single-Use	Yes	Yes	Same

Manufacturer	Fortimedix Surgical B.V.	TransEnterix, Inc.	Significant Differences
Trade Name	**FMX314 Surgical Platform (FMX314 Instruments)**	**SPIDER™ Surgical Instruments**	
Maximum Voltage Rating	< 3500 volts	< 3500 volts	Same
Shelf Life	2 years	Unknown	N/A

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of the FMX314 Surgical Platform and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, Fortimedix Surgical completed a number of non-clinical performance tests. The FMX314 Surgical Platform meets all the requirements for overall design, sterilization, biocompatibility, and electrical safety results confirming that the design output meets the design inputs and specifications for the device.

The FMX314 Surgical Platform passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Biocompatibility testing for the FMX314 Instruments including cytotoxicity, sensitization, intracutaneous reactivity, and systemic toxicity per ISO 10993-1: *PASSED all testing*
- Electrical safety testing according to applicable sections for the FMX314 Surgical Platform per AAMI/ANSI ES60601-1: *PASSED required testing*
- Electrical safety testing according to applicable sections for the FMX314 Surgical Platform per IEC 60601-2-2: *PASSED required testing*
- Electrical safety testing according to applicable sections for the FMX314 Surgical Platform per IEC 60601-2-18: *PASSED required testing*
- Axial Guidance Verification and Durability of the FMX314 Introducer complies with the requirements for friction and dynamic-static friction placed through a number of cycles: *PASSED required testing*
- Triangulation and Range of Motion to verify that the FMX314 Instruments lateral, superior/inferior, and anterior/posterior mobility is maintained: *PASSED required testing*
- Instrument Stiffness is verified that the maximal axial load forces, minimum torqued, and the minimum distal articulation stiffness meet specifications: *PASSED required testing*
- Cleaning and Reprocessing for the FMX314 Introducer meet all requirements for reprocessing: *PASSED required testing*
- Sterilization Testing of the FMX314 Instruments and FMX314 Hub Cap & Sealing Unit to ISO 11137 standard for radiation sterilization meeting an SAL of 10^{-6}: *PASSED required testing*

- Shelf Life Testing for a period of two (2) years for sterilized product including the FMX314 Instruments and FMX314 Hub Cap & Sealing Unit including functionality testing: *PASSED all testing*

10. Clinical Performance Data

There was no human clinical testing performed to support the medical device as the indications for use is equivalent to the predicate device. However, detailed thorough performance bench tests were completed including *ex vivo* cadaver studies and *in vivo* animal studies (minimally-invasive laparoscopic abdominal surgery in a animal model**)** that were performed using the subject device, FMX314 Surgical Platform.

- Performance of the FMX314 Surgical Platform in an animal model *in vivo* study confirmed the use, functionality, and operation of the device during single port laparoscopic surgery through cuts of defined length with different temperature/energy levels with subsequent analysis. The analysis of the testing was performed grossly and histopathologically utilizing a representative instrument for testing. The tissue testing criteria for the study included cut accuracy, coagulation depth, thermal spread and damage, tissue adherence to instruments, and compatibility across representative energy settings. The animal study was completed according to Good Laboratory Practices (GLP) with proper handling of the study animals.

- An acute study was completed on animal models as described previously. The animals were each processed through a surgical procedure to have the liver accessed for the use of the FMX314 Surgical Platform according to the tissue/performance testing requirements. The endpoints of the study all passed defined criteria supporting performance testing through use of an *in vivo* animal model.

- A chronic study was completed in the same manner as the afore-mentioned acute study with the difference being that the animals were not immediately euthanized after the completion of the procedure. The endpoints of the study all passed defined criteria supporting performance testing through use of an *in vivo* animal model.

- A human cadaver study was performed to evaluate real-life conditions for anatomical landmarks and dimensions that would be expected in a human patient. The goal was to evaluate the FMX314 Surgical Platform for dimensional and functional adequacy regarding triangulation, articulation, and length of instruments. The human cadaver study supports that relevant human landmarks in the abdominal cavity were reachable with no incidents. No negative feedback was given by the user for any aspect of landmark access, manipulation of the instruments, articulation of the instruments, and generally the overall laparoscopic surgical procedure.

- Validation of the FMX314 Surgical Platform was performed by completing a usability study from the unpacking, installation, through the surgical procedure, and reprocessing of the finished device. The intended user was observed during use of the device including feedback that was obtained from each of the users for analysis. Usability assessment was made during the animal model *in vivo* study and *ex vivo* cadaver study to obtain feedback on completion of all task selections.

The sponsor has provided each of the final testing reports that contain a description of the test objective, test article, test method, acceptance criteria, results, analysis, and conclusion such that these testing were performed to demonstrate the functionality and mechanical safety of the subject device, FMX314 Surgical Platform. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Conclusion

The results of the performance bench tests including *ex vivo* cadaver studies and *in vivo* animal studies demonstrated that the FMX314 Surgical Platform is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate devices.