May 8, 2018

Fetzer Medical GmbH & Co. KG
Harald Jung
Manager Quality/Regulatory Affairs
Unter Buchsteig 5
Tuttlingen, Baden-Wuerttemberg 78532
Germany

Re: K172661
Trade/Device Name: Fetzer Medical Gynecological Forceps
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: II
Product Code: HCZ
Dated: April 6, 2018
Received: April 10, 2018

Dear Harald Jung:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Charles Viviano -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172661

Device Name
Fetzer Medical Gynecological Forceps

Indications for Use *(Describe)*
Fetzer Medical Gynecological Forceps are hand-held instruments with dual blades that are indicated for pulling, grasping, holding, or compressing tissue during gynecological 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
(K172661)

1. Submitter Information

Submitter: Fetzer Medical GmbH & Co. KG
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GERMANY

Contact Person: Harald Jung, Manager Quality & Regulatory
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2. Date Prepared

May 7, 2018

3. Device Information

Trade Names:	Fetzer Medical Gynecological Forceps
Common Name:	Vulsellum Forceps, Tenaculum Forceps, Hysterectomy Forceps
Regulation Number:	21 CFR 884.4530
Regulation Name:	Obstetric-Gynecologic Specialized Manual Instrument
Product Code:	HCZ (Forceps, Surgical, Gynecological)
Regulatory Class:	II

4. Predicate Device:

Integra ® Gynecological Forceps (K134047) manufactured by Integra Lifesciences Corporation. The predicate device has not been subject to any design related recalls.

5. Device Description:

This 510(k) covers 31 devices a total of 132 variants representing three general designs (vulsellum, tenaculum, and hysterectomy). These products are reusable manual surgical instruments to be used in gynecological procedures. They are scissor-like, self-retaining devices with ring handles and two blades and made of high-grade stainless steel or titanium. They are available in various sizes with different blade designs at the distal end (e.g., straight or curved). Some of these devices have an additional grasping claw at the distal end. The blades are heavily serrated or may have a profiled longitudinal groove to provide extra grip of the organ.

The subject devices vary in the jaw configurations and curvature to meet the surgeon's needs and preferences, based on individual, anatomical variations of the patients. The products are sold non-sterile and can be reused (cleaned and sterilized) according to the instructions for use.

6. Indications for Use

Fetzer Medical Gynecological Forceps are hand-held instruments with dual blades that are indicated for pulling, grasping, holding, or compressing tissue during gynecological procedures.

7. Comparison of Intended Use and Technological Characteristics of the Subject Device and Predicate Device

Device:	K172661 – Subject device	K134047 – Predicate device
Indications for Use	Fetzer Medical Gynecological Forceps are hand-held instruments with dual blades that are indicated for pulling, grasping, holding, or compressing tissue during gynecological procedures.	Integra gynecological surgical forceps are hand-held instruments with dual blades that are indicated for pulling, grasping, holding, or compressing tissue during gynecological procedures.
General design	Same as the predicate device	Vulsellum, tenaculum, and hysterectomy
Device version	Same as the predicate device	Multiple variants for each general design
Dimensions	Same as the predicate device	Ranged for each general design
Jaw configuration	Same as the predicate device	Ranged for each general design
Curvature	Same as the predicate device	Ranged for each general design
Material	Stainless steel or titanium	Stainless steel
Reprocessing step	Same as the predicate device	Cleaning and steam cycle

The subject and predicate devices have the same intended use for pulling, grasping, holding, or compressing tissue during gynecological procedures.

The subject and predicate devices have multiple variants representing the same general designs (vulsellum, tenaculum, and hysterectomy) and comparable reprocessing procedures. There are differences in dimensions, jaw configuration and curvature between the subject and predicate devices. However, these differences in technological characteristics do not raise different questions of safety and effectiveness. In fact, both have ranges of dimensions, jaw configuration and curvature to meet different clinical needs.

One version of the subject devices is manufactured titanium, but the predicate device is not. This difference does not raise different questions of safety and effectiveness, as titanium is widely used in surgical devices.

The differences between the subject and predicate devices can be evaluated by biocompatibility information and bench performance testing.

8. Summary of Non-Clinical Performance Testing

The following studies have been performed to support substantial equivalence to the predicate device:

- Cytotoxicity testing per ISO 10993-5:2009
- Cleaning and sterilization validation study to meet the requirements in the following documents:
  - FDA Guidance – “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling” issued March 17, 2015
  - AAMI TIR12:2010
- Bench performance tests:
  - Boiling water test for corrosion per ASTM F1089-10
  - Elasticity test per DIN 96198-3

In addition, the biocompatibility information provided in cleared devices (K160104, K150468, and K120492) were leveraged in the current submission to support substantial equivalence to the predicate device.

9. Conclusion

The subject and predicate devices have the same intended use and fundamental technological characteristics. The differences in technological characteristics between subject and predicate devices do not raise different questions of safety and effectiveness. The performance data demonstrate that the subject devices are substantially equivalent to the predicate device.