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

June 28, 2016

Ningbo Feite Medical Device Co., Ltd
% Charles Shen
Official Correspondent
Manton Business and Technology Services
37 Winding Ridge
Oakland, NJ 07436

Re: K152350
Trade/Device Name: Regular and Special Umbilical Cord Clamp and Cutter
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: Class II
Product Code: NBZ
Dated: May 27, 2016
Received: May 27, 2016

Dear Charles Shen,

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,

Benjamin R. Fisher -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152350

Device Name
Regular and Special Umbilical Cord Clamp and Cutter

Indications for Use *(Describe)*
Regular and Special Umbilical Cord Clamp and Cutter are intended for use in simultaneously clamping and cutting the umbilical cord of the new born baby at delivery

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted
In accordance with the requirements of 21CFR 807.92

5.1 Submitter & Foreign Manufacture Identification

Ningbo Feite Medical Device Co., Ltd.
Tongpenzha, Zhonggongmiao Street, Yinzhou District, 315192, Ningbo, Zhejiang Province, China

5.2 Contact Person

Charles Shen
Manton Business and Technology Services
37 Winding Ridge, Oakland, NJ 07436
Tel: 608-217-9358
Email: cyshen@aol.com

5.3 Date of Summary: July 29, 2014

5.4 Device Name:

Proprietary Name:	Regular and Special Umbilical Cord Clamp and Cutter
Common Name:	Clamp and Cutter, Umbilical
Classification Name:	Clamp and Cutter, Umbilical
Device Classification:	II
Regulation Number:	21 CFR 884.4530
Panel: General	Obstetrics/Gynecology
Product Code:	NBZ

5.5 Predicate Device Information:

(1) K011621, “Koala Clamp and Cutter”, manufactured by “Maternus Inc.” in San Antonio, TX.

5.6 Device Description:

“Regular and Special Umbilical Cord Clamp and Cutter” manufactured by “Ningbo Feite Medical Device Co., Ltd.” are a single use, disposable, molded plastic device, unit packaged and sterile, intended to use for the simultaneously cut and clamp umbilical cord of the new born baby at delivery.

“Special Umbilical Cord Clamp and Cutter” are comprised of the exact same part as “Regular Umbilical Cord Clamp and Cutter”, with the addition of an electronic clock. The time is automatically recorded when the cutting is performed.

Section 5: 510(k) Summary

5.7 Intended Use:

Regular and Special Umbilical Cord Clamp and Cutter are intended for use in simultaneously clamping and cutting the umbilical cord of the new born baby at delivery

5.8 Technological Comparison with Predicate Device

The following table shows similarities and differences of use, design, and material between our device and the predicate devices.

Table 5.1: Comparison of Intended Use, Design, Material, and Processing

Description	Subject Device	Predicate Device (K011621)
Indication for Use	Regular and Special Umbilical Cord Clamp and Cutter are intended for use in simultaneously clamping and cutting the umbilical cord of the new born baby at delivery	The indications for Use of the Koala Clamp & Cutter are to simultaneously cut and clamp umbilical cord.
Target Population	All vaginal births	All vaginal births
Basic Design	Combine clamp and cutter in the same unit	Combine clamp and cutter in the same unit
Clamp Material	Plastic	Plastic
Cutter Material	Stainless steel	Stainless steel
Dimension	Clamp @ baby side: Arm 1: 37.20 mm; Arm 2: 38.05 mm Clamp @ placenta side: Arm 1: 34.70 mm, Arm 2: 36.07 mm Blade: 44 x 16 mm	74 x 50.6 x 32.9 mm
Single Use	Yes	Yes
Biocompatible	Yes	Yes
Sterile	Sterilization with EO	Sterilization with EO
Anatomical Site	Umbilical cord	Umbilical cord
Other feature	Special Umbilical Cord Clamp and Cutter has clock function	No

Section 5: 510(k) Summary

Our device is essentially identical to the predicate device in terms of indications for use, design, material, and processing between our device and the predicate devices. Minor differences do not impact the safety and effectiveness of the device.

5.9 Summary of Device Testing:

Bench testing was performed to ensure that the "Regular and Special Umbilical Cord Clamp and Cutter" met its specifications. All tests were verified to meet acceptance criteria. Biocompatibility testing demonstrated that the devices are biocompatible.

5.10 Conclusion

The "Regular and Special Umbilical Cord Clamp and Cutter" are substantially equivalent to the predicate device.