Revision of Precautions to the Package Inserts of Ultrasonic Surgical Aspirator Devices

1. Background

The U.S. Food and Drug Administration (FDA) reported that "when used for hysterectomy or myomectomy in women with uterine fibroids, laparoscopic power morcellation poses a risk of spreading unsuspected cancerous tissue, notably uterine sarcomas, beyond the uterus" in regards to the use of power morcellators[1] in April 2014 (Reference 1). Based on this report, Ministry of Health, Labour and Welfare (MHLW), Pharmaceuticals and Medical Devices Agency (PMDA), and relevant academic societies reviewed the information and the Administrative Notice (Reference 2) to revise the precautions of the package inserts was issued in July 2016 by Medical Device Evaluation Division and Safety Division, Pharmaceutical Safety and Environmental Health Bureau, MHLW to contraindicate the use of power morcellators if the patient has or is suspected to have malignant tumors.

FDA issued a guidance on October 30, 2017 stating that ultrasonic surgical aspirator devices should not be used in the removal of uterine fibroids (Reference 3).

2. FDA's guidance regarding ultrasonic surgical aspirator devices

The following is a summary of the guidance that FDA issued regarding ultrasonic surgical aspirator devices:

- Ultrasonic surgical aspirator devices are surgical tools intended to fragment, emulsify, and aspirate tissue through the delivery of ultrasound energy through an oscillating tip.
- Ultrasonic surgical aspirator devices may be indicated for use in a wide range of surgical applications, such as neurosurgery, orthopedic surgery, laparoscopic surgery, open surgery, and gynecologic surgery.
- Ultrasonic surgical aspirator devices are sometimes used for debulking[2].
- Use of an ultrasonic surgical aspirator to fragment and emulsify malignant tumor could result in dissemination of this cancer.
- FDA is not aware of ultrasonic surgical aspirator devices being used in the removal of uterine fibroids. Since there are currently no reliable preoperative screening

[1] Active cutting instruments used by laparoscopically inserting into the body cavity to remove tissues
[2] Removing a portion of a tumor. The remaining tumor may be treated by two-stage resection, chemotherapy or radiation therapy etc.

procedures to detect uterine sarcoma in women with presumed benign fibroids, use of an ultrasonic surgical aspirator during treatment for symptomatic uterine fibroids on a woman with an occult uterine sarcoma could result in dissemination of this cancer.

- The risk of cancer dissemination outweighs any potential benefits, particularly since there are alternative treatment options available.

3. Actions to be taken in Japan

Following the FDA's guidance issued on October 30, 2017, a review was conducted to determine the necessity of actions to be taken regarding ultrasonic surgical aspirator devices in Japan. As a result of this review, it was concluded that a revision of precautions of the package inserts is necessary in consideration of the risk of dissemination of unsuspected uterine sarcoma when the device is used to patients with uterine fibroids.

1) Products subject to the revision

There are a number of medical devices that utilize ultrasonic energy. In general for surgical use, there are devices with the wavelength of high-frequency bands that generate joule heating or sparks, etc. to use for cutting and cauterization of tissue; and devices with the wavelength of low-frequency bands that generate vibrations to make tissue absorb energy inside that results in fragmenting and emulsifying of tissue. Fragmenting and emulsifying of tissue is characterized by causing fewer haemorrhage or cytopathic changes. The risk of dissemination occurs when fragmenting and emulsifying tumor tissues by sonication, therefore the products subjected to the revision are the medical devices with the function of fragmenting and emulsifying of tissues by sonication, regardless of with or without the function of suction/aspiration.

The medical devices currently known to be subjected to the above are listed in the reference 4.

2) Revision based on the usage

Today in Japan, preoperative examinations such as magnetic resonance imaging (MRI) scans, cytodiagnosis, and measurements of serum low-density lipoprotein (LDL) levels are conducted in patients with uterine fibroids to rule out malignancy. However, there were cases of malignancy identified only after operations, as making a definitive diagnosis before extirpation was not possible. A case similar to these is described in the

July 2016 Administrative Notice to revise the precautions of the package inserts, which states that power morcellators should not be used during laparoscopic hysterectomy or myomectomy in women with uterine fibroids if the patient is suspected to have malignant tumors. In clinical settings as well, some precautions such as those to rule out the possibility of malignancy through preoperative MRI or pathological diagnosis in light of the risk of cancer cells metastasizing, or to obtain full informed consent about risk of malignant lesion that is not possible to diagnose even with thorough preoperative evaluations, or risk of poor prognosis etc. are mentioned in the report, Use of Power Morcellators for Laparoscopic Hysterectomy or Myomectomy (Journal of the Japan Society of Gynecologic and Obstetric Endoscopy and Minimally Invasive Therapy, Vol. 30, No.1, 2014) by The Japan Society of Gynecologic and Obstetric Endoscopy and Minimally Invasive Therapy, and in Training Note No. 96, Uterine Fibroids published by the Japan Association of Obstetricians and Gynecologists.

Meanwhile, treatments using ultrasonic surgical aspirator devices for uterine fibroids are not mentioned in clinical practice guidelines etc. of relevant medical associations, and are not a standard procedure according to expert advice. Therefore, in light of how use of ultrasonic surgical aspirator devices for removal of uterine fibroids is rare in clinical practice and the availability of alternative treatment options other than ultrasonic surgical aspirator devices, use of ultrasonic surgical aspirator devices for removal of uterine fibroids where the possibility of causing malignant changes cannot be ruled out is not recommended.

3) Draft revisions to the Package insert

The following language should be added to the Contraindications section of the package insert.

<u>This product should not be used to emulsify or fragment uterine fibroids for which the possibility of causing malignant changes cannot be ruled out. [There is a risk of cancer cells metastasizing due to dispersion of tissue fragments.]</u>

Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy: FDA Safety Communication

FDA issued an **updated safety communication (/MedicalDevices/Safety/AlertsandNotices/ucm424443.htm)** on November 24, 2014

Date Issued: April 17, 2014

Audience:

- Health Care Providers
- Medical Professional Associations
- Cancer Advocacy Organizations
- Health Care Facilities/Hospitals
- Women with Symptomatic Uterine Fibroids who are Considering Surgical Options
- Manufacturers of Devices used for Minimally Invasive Surgeries

Medical Specialties: Pathology, Internal Medicine, Nursing, Obstetrics/Gynecology, Oncology

Product:
Laparoscopic power morcellators are medical devices used during different types of laparoscopic (minimally invasive) surgeries. These can include certain procedures to treat uterine fibroids, such as removing the uterus (hysterectomy) or removing the uterine fibroids (myomectomy). Morcellation refers to the division of tissue into smaller pieces or fragments and is often used during laparoscopic surgeries to facilitate the removal of tissue through small incision sites.

Purpose:
When used for hysterectomy or myomectomy in women with uterine fibroids, laparoscopic power morcellation poses a risk of spreading unsuspected cancerous tissue, notably uterine sarcomas, beyond the uterus. Health care providers and patients should carefully consider available alternative treatment options for symptomatic uterine fibroids. Based on currently available information, the FDA discourages the use of laparoscopic power morcellation during hysterectomy or myomectomy for uterine fibroids.

Summary of Problem and Scope:
Uterine fibroids are noncancerous growths that develop from the muscular tissue of the uterus. Most women will develop uterine fibroids (also called leiomyomas) at some point in their lives, although most cause no symptoms[1]. In some cases, however, fibroids can cause symptoms, including heavy or prolonged menstrual bleeding, pelvic pressure or pain, and/or frequent urination, requiring medical or surgical therapy.

Many women choose to undergo laparoscopic hysterectomy or myomectomy because these procedures are associated with benefits such as a shorter post-operative recovery time and a reduced risk of infection compared to abdominal hysterectomy and myomectomy[2]. Many of these laparoscopic procedures are performed using a power morcellator.

A number of additional treatment options are available for women with symptomatic uterine fibroids including traditional surgical hysterectomy (performed either vaginally or abdominally) and myomectomy, laparoscopic hysterectomy and myomectomy without morcellation, laparotomy using a smaller incision (minilaparotomy), deliberate blocking of the uterine artery (catheter-based uterine artery embolization), high-intensity focused ultrasound, and drug therapy. Evidence demonstrates that, when feasible, vaginal hysterectomy is associated with comparable or better results and fewer complications than laparoscopic or abdominal hysterectomy[3].

Importantly, based on an FDA analysis of currently available data, it is estimated that 1 in 350 women undergoing hysterectomy or myomectomy for the treatment of fibroids is found to have an unsuspected uterine sarcoma, a type of uterine cancer that includes leiomyosarcoma. **If laparoscopic power morcellation is performed in women with unsuspected uterine sarcoma, there is a risk that the procedure will spread the cancerous tissue within the abdomen and pelvis, significantly worsening the patient's likelihood of long-term survival. For this reason, and because there is no reliable method for predicting whether a woman with fibroids may have a uterine sarcoma, the FDA discourages the use of laparoscopic power morcellation during hysterectomy or myomectomy for uterine fibroids.**

Recommendations for Health Care Providers:

- Be aware that based on currently available information, the FDA discourages the use of laparoscopic power morcellation during hysterectomy or myomectomy for the treatment of women with uterine fibroids.
- Do not use laparoscopic uterine power morcellation in women with suspected or known uterine cancer.
- Carefully consider all the available treatment options for women with symptomatic uterine fibroids.
- Thoroughly discuss the benefits and risks of all treatments with patients.
- For individual patients for whom, after a careful benefit-risk evaluation, laparoscopic power morcellation is considered the best therapeutic option:
    - Inform patients that their fibroid(s) may contain unexpected cancerous tissue and that laparoscopic power morcellation may spread the cancer, significantly worsening their prognosis.
    - Be aware that some clinicians and medical institutions now advocate using a specimen "bag" during morcellation in an attempt to contain the uterine tissue and minimize the risk of spread in the abdomen and pelvis.

Recommendations for Women:

- Ask your health care provider to discuss all the options available to treat your condition and discuss the risks and benefits of each.

- If laparoscopic hysterectomy or myomectomy is recommended, ask your health care provider if power morcellation will be performed during your procedure, and to explain why he or she believes it is the best treatment option for you.
- If you have already undergone a hysterectomy or myomectomy for fibroids, tissue removed during the procedure is typically tested for the presence of cancer. If you were informed these tests were normal and you have no symptoms, routine follow-up with your physician is recommended. Patients with persistent or recurrent symptoms or questions should consult their health care provider.

FDA Actions:
The FDA is concerned about women undergoing laparoscopic power morcellation for the treatment of uterine fibroids and the risk of inadvertent spread of unsuspected cancer to the abdominal and pelvic cavities. In an effort to enhance understanding of the problem and provide information on the appropriate use of laparoscopic power morcellators, the FDA:

- Instructed manufacturers of power morcellators used during laparoscopic hysterectomy and myomectomy to review their current product labeling for accurate risk information for patients and providers;
- Will convene a public meeting of the Obstetrics and Gynecological Medical Device Advisory Committee to discuss: 1) the clinical role of laparoscopic power morcellation in the treatment of uterine fibroids, 2) whether surgical techniques and/or use of accessories, such as morcellation/specimen bags, can enhance the safe and effective use of these devices, and 3) whether a “boxed warning” related to the risk of cancer spread should be required for laparoscopic power morcellators;
- Will continue to review adverse event reports, peer-reviewed scientific literature, and information from patients, health care providers, gynecologic and surgical professional societies, and medical device manufacturers.

Reporting Problems to the FDA:
Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. If you suspect that a morcellator and/or specimen bag has malfunctioned or contributed to a serious injury or adverse outcome, the FDA encourages you to file a voluntary report through **MedWatch, the FDA Safety Information and Adverse Event Reporting program (/Safety/MedWatch/HowToReport/ucm2007306.htm)**.

Health care professionals employed by facilities that are subject to the **FDA's user facility reporting requirements (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm)** should follow the reporting procedures established by their facilities.

Other Resources:

- **Society of Gynecologic Oncology (SGO)’s position statement on morcellation published in December 2013 (https://www.sgo.org/newsroom/position-statements-2/morcellation/)**
- **American College of Obstetricians and Gynecologists (ACOG)’s Statement on Choosing the Route of Hysterectomy for Benign Disease November 2009 (Reaffirmed 2011) (https://www.acog.org/Resources_And_Publications/Committee_Opinions/Committee_on_Gynecologic_Practice/Choosing_the_Route_of_Hysterectomy_for_Benign_Disease)**
- **American Association of Gynecologic Laparoscopists (AAGL)’s AAGL Member Update: Disseminated Leiomyosarcoma With Power Morcellation 2014 (http://www.aagl.org/aaglnews/aagl-member-update-disseminated-leiomyosarcoma-with-power-morcellation/) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**

References:

[1] NIH Fact Sheet on Uterine Fibroids. March 2013. Available at **http://report.nih.gov/nihfact-sheets/viewfactsheet.aspx?csid=50 (http://report.nih.gov/nihfactsheets/viewfact-sheet.aspx?csid=50)**

[2] Nieboer TE, Johnson N, Lethaby A, et al. Surgical approach to hysterectomy for benign gynecological disease. Cochrane Database Syst Rev. 2009;(3):CD003677.

[3] Ibid.

Contact Information:

If you have questions about this communication, please contact the Center for Devices and Radiological Health's Division of Industry and Consumer Education (DICE) at **DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV)**, 800-638-2041 or 301-796-7100.

Additional Information

- **Quantitative Assessment of the Prevalence of Unsuspected Uterine Sarcoma in Women Undergoing Treatment of Uterine Fibroids - Summary and Key Findings (PDF - 253KB) (/downloads/MedicalDevices/Safety/AlertsandNotices/UCM393589.pdf)**

More in Safety Communications (/MedicalDevices/Safety/AlertsandNotices/default.htm)

Information About Heparin (/MedicalDevices/Safety/AlertsandNotices/ucm135345.htm)

Preventing Tubing and Luer Misconnections (/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm)

Ministry of Health, Labour and Welfare

Translated by **Pharmaceuticals and Medical Devices Agency**

Safety Division, Pharmaceutical Safety and Environmental Health Bureau

Office of Safety I

July 25, 2016

Administrative Notice

To: Members (of the Associations/Committees listed in Appendix 1)

Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare

Safety Division, Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare

Precautions in the Package Insert of Power Morcellators

The U.S. Food and Drug Administration (FDA) has reported that “when used for hysterectomy or myomectomy in women with uterine fibroids, power morcellators pose a risk of spreading unsuspected cancerous tissue notably uterine sarcomas, beyond the uterus” in regards to the use of power morcellators (active cutting instruments used by laparoscopically inserting into the body cavity to remove tissues).

Given the above, please note that the “Precautions” in the package insert of power morcellators newly approved or certified in the future will be handled as follows in order to ensure proper use after marketing.

Furthermore, we inform you that similar administrative notices have been sent to Association of Registered Certification Bodies under PMDAct (ARCB) and to Pharmaceuticals and Medical Devices Agency.

1. In the “Contraindications” section of the package insert for power morcellators, the following text should be added:

   The product should not be used if the patient has or is suspected to have malignant tumors. [There is a risk of cancer cells metastasizing due to dispersion of tissue fragments.]

2. In the “Important Precautions” section of the Precautions in the package insert for power morcellators, the following text should be added:

   Uterine tissue may contain unsuspected cancer. The use of the product may spread the cancer, and decrease the long-term survival of patients. This information should be shared with patients, and informed consent should be obtained before the use of the product.

(Appendix 1)

The Japan Federation of Medical Devices Associations
American Medical Devices and Diagnostics Manufacturers' Association
Medical Equipment Committee of the European Business Council in Japan

Contains Nonbinding Recommendations

Product Labeling for Certain Ultrasonic Surgical Aspirator Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on October 30, 2017.

The draft of this document was issued on November 10, 2016.

For questions about this document, contact the Obstetrics-Gynecology Devices Branch, 301-796-7030 for gynecologic indications, or the General Surgery Devices Branch 2, 301-796-6970 for general surgical indications.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2016-D-3275. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number 1500072 to identify the guidance you are requesting.

Product Labeling for Certain Ultrasonic Surgical Aspirator Devices

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The Food and Drug Administration (FDA) is issuing this guidance to recommend the addition of a specific safety statement to the product labeling of certain ultrasonic surgical aspirator devices. Ultrasonic surgical aspirator devices are surgical tools intended to fragment, emulsify and aspirate hard and soft tissue. These devices can be used in many different surgical specialties for a wide range of procedures, including the debulking of malignant tumors. Ultrasonic surgical aspirators cause tissue fragmentation through the delivery of ultrasound energy to target tissue through an oscillating tip. Tissue fragments are aspirated through the inner lumen of the device. This mechanism of action creates the potential for tissue dissemination. The incorporation of suction/aspiration reduces but cannot eliminate this potential.

In light of the risk of tissue dissemination from use of these devices, the FDA is providing a specific labeling recommendation in this guidance to promote the safe and effective use of ultrasonic surgical aspirator devices.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

Ultrasonic surgical aspirator devices may be indicated for use in a wide range of surgical applications, including but not limited to neurosurgery, plastic and reconstructive surgery, orthopedic surgery, laparoscopic surgery, open surgery, and gynecologic surgery. Because ultrasonic surgical aspirator devices use an oscillating tip to cause tissue fragmentation through

the delivery of ultrasound energy to target tissue, there is the potential for tissue dissemination that is mitigated but not completely eliminated by the use of suction/aspiration.

FDA is aware that ultrasonic surgical aspirator devices are sometimes used to treat advanced malignancy through cytoreduction (also known as debulking). In these cases, the device is used to remove a portion of a malignant tumor that cannot be completely excised, in an effort to enhance the effectiveness of ancillary treatments (such as radiation or chemotherapy). When used in advanced cancers, the risk of adverse clinical effects from tissue dissemination may be small compared to the device's potential benefits, such as more extensive tumor debulking, no/minimal collateral thermal damage, and the ability to avoid resection/removal of organs.

However, in certain clinical circumstances, the unintended dissemination of cancerous cells may have a significant adverse effect that outweighs any demonstrated benefits. FDA is aware that labeling of certain ultrasonic surgical aspirator devices allows for use in the removal of uterine fibroids, although this use may not be explicitly stated in the labeling and FDA is not aware of these devices being used for this purpose.[1] There are currently no reliable preoperative screening procedures to detect uterine sarcoma in women with presumed benign fibroids. Use of an ultrasonic surgical aspirator during treatment for symptomatic uterine fibroids on a woman with an occult uterine sarcoma could result in dissemination of this cancer. This risk of cancer dissemination outweighs any potential benefits in this patient population, particularly since there are alternative treatment options available.

For these reasons, FDA recommends that the labeling of certain ultrasonic surgical aspirator devices include a contraindication against use of the devices for removal of uterine fibroids.

III. Scope

Ultrasonic surgical aspirator devices may have general indications for use (e.g., laparoscopic surgery, open surgery) or specific indications for use (e.g., gynecologic surgery). This guidance, and the labeling recommendation below, applies to ultrasonic surgical aspirator devices with indications for use in laparoscopic surgery, open surgery, or gynecologic surgery as such surgeries can include gynecologic procedures. These devices are regulated under several different product codes, including LFL (Instrument, Ultrasonic Surgical) and NLQ (Scalpel, Ultrasonic, Reprocessed). Some devices regulated under these product codes may utilize different technology (e.g., they do not aspirate), and would not fall within the scope of this guidance.

[1] On November 25, 2014, FDA issued the "Immediately in Effect Guidance Document: Product Labeling for Laparoscopic Power Morcellators" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM424123.pdf) to address new scientific information that represents a significant change to the benefit/risk profile for laparoscopic power morcellators (LPM). Specifically, FDA reviewed scientific information that suggests that the use of LPMs contributes to the dissemination and upstaging of an occult uterine malignancy in women undergoing laparoscopic gynecologic surgery for presumed fibroids. FDA is generally not aware of reports of dissemination or upstaging of occult uterine malignancies related to ultrasonic surgical aspirators at this time. FDA is recommending the contraindication in this guidance, rather than the contraindication in the LPM guidance, in light of the fact that ultrasonic surgical aspirators are generally not intended nor used for the removal of uterine fibroids.

This guidance does not apply to ultrasonic surgical aspirator devices with an indication for use only for other surgical subspecialties, e.g., gastrointestinal and affiliated organ surgery, urological surgery, neurosurgery. For example, this guidance would not apply to devices indicated only for neurosurgical fragmentation and aspiration.

IV. Recommended Labeling Statement

FDA recommends that manufacturers of ultrasonic surgical aspirator devices with indications for use in laparoscopic surgery, open surgery, or gynecologic surgery prominently include the following Contraindication in their product labeling:

> ***CONTRAINDICATION: This ultrasonic surgical aspirator device is not indicated for and should not be used for the fragmentation, emulsification, and aspiration of uterine fibroids.***

In addition to including the above Contraindication in the product labeling, we recommend manufacturers review and update other portions of their labeling to be consistent with this Contraindication. For example, a manufacturer may revise the list of procedures in the labeling for which the ultrasonic surgical aspirator can be utilized.

FDA believes accurate product labeling is important to make health care providers and patients aware of situations when these devices should not be used. FDA believes that the Contraindication is important for the safe and effective use of these ultrasonic surgical aspirator devices.

Within 120 days of the publication of this guidance, a manufacturer with an existing 510(k) clearance should: 1) add the Contraindication to its labeling; 2) submit both the current labeling and revised labeling to the Center for Devices and Radiological Health (CDRH); and 3) provide updated labeling to purchasers of these ultrasonic surgical aspirator devices that have already been distributed.[2]

If a manufacturer with an existing 510(k) clearance adds the Contraindication listed above, FDA does not intend to object if such labeling changes are submitted as an amendment ("add to file") to the existing 510(k) rather than as a new 510(k). We recommend that manufacturers bundle 510(k) amendments for these labeling changes as appropriate.

In addition, manufacturers submitting a new 510(k) for a new or significantly modified device should include these labeling recommendations in the submission.

[2] FDA recommends that a manufacturer provide updated labeling in a way to help ensure purchasers are aware of it, such as posting the updated labeling on the manufacturer's website and notifying purchasers that they can access the updated labeling on that website.

Nonproprietary name	Marketing authorization holder	Product name	Approval/certification number etc.
Ultrasonic surgical aspirator devices	Amco Inc.	Ultrasonic Aspirators CUSA Excel	21100BZY00633000
Ultrasonic surgical aspirator devices	Hitachi, Ltd.	SONOP 5000	21300BZZ00029000
Ultrasonic surgical aspirator devices	Olympus Medical Systems Corp.	Ultrasonic Surgical System SonoSurg	21400BZZ00559000
Ultrasonic surgical aspirator devices	Stryker Japan K.K.	Sonopet UST-2001 Alpha	22500BZX00508000
Ultrasonic surgical aspirator devices	EPJ Medical Service Co., Ltd.	Ultrasonic Tissue Ablation System CUSA Clarity	23000BZX00065000