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

November 13, 2015

Nvision Medical
% Cindy Domecus
Principal
Domecus Consulting Services LLC
1171 Barroilhet Drive
Hillsborough, California 94010

Re: K151275
Trade/Device Name: MAKO Device
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope And Accessories
Regulatory Class: Class II
Product Code: HIH
Dated: October 14, 2015
Received: October 15, 2015

Dear Cindy Domecus:

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)*
K151275

Device Name
MAKO Device

Indications for Use *(Describe)*
The MAKO Device is a hysteroscope accessory, placed through the working channel of a hysteroscope to obtain samples from the proximal fallopian tube for cytological evaluation.

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

I. SUBMITTER

510(k) Owner:
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Date Prepared:
May 11, 2015

II. DEVICE

Name of Device:	MAKO Device
Common or Usual Name:	Hysteroscope Accessory
Classification Name:	Hysteroscope and accessories (884.1690)
Regulatory Class:	II
Product Code:	HIH

III. PREDICATE DEVICE

Substantial equivalence was claimed to the following predicate device:

510(k) Number, Company	Trade Name	Model Number
K132384 EndoSee	U-Scope™ 8000 HSC+EMB Cannula	8000

IV. DEVICE DESCRIPTION

The MAKO Device is a hysteroscope accessory intended to collect cell samples from the proximal fallopian tube. The device is comprised of a catheter and a handle. The catheter includes a balloon, a shaft (which is made up of a stainless steel tube and a Nylon tube), a sheath (Nylon 12), and a sheath knob (Polycarbonate). The handle includes a drive wheel and an extension tube that is attached to a luer in the handle body. The extension tube attaches to a commercially available inflation device via a commercially available 3-way stopcock.

In summary, the physician inserts the MAKO Device into the working channel of the hysteroscope until the distal tip of the catheter is positioned immediately proximal to the ostium of the fallopian tube. Then, the balloon is advanced into the proximal portion of the fallopian tube and cells are collected on its surface.

The MAKO Device is a sterile, single-use device. The device is terminally sterilized using ethylene oxide (EO).

The device is intended for use in the hospital/clinic/physician's office. The duration and type of contact is classified as follows:

- Category: External Communicating Device
- Contact: Mucosal membrane
- Duration: A – Less than 24 hours

V. INTENDED USE/INDICATIONS FOR USE

The *indications for use* for the subject device are as follows:

The MAKO Device is a hysteroscope accessory, placed through the working channel of a hysteroscope to obtain samples from the proximal fallopian tube for cytological evaluation.

The *indications for use* are different than the predicate, in that the indication for use for the subject device 1) does not contain information pertaining to indications for the hysteroscope, as the device does not include a hysteroscope, but rather, is used through the working channel of a commercially available hysteroscope, and 2) refers to the collection of samples from the proximal fallopian tube instead of the uterus.

Not including information pertaining to the indications for use for the hysteroscope is not a substantive issue, as the subject device will be used through the working channel of a commercially available hysteroscope, which will include indications for use for the hysteroscope that were cleared by FDA.

Since the proximal fallopian tube represents a different anatomical location than the uterus, the FDA guidance document, "General/Specific Intended Use," (issued November 4, 1998) was used to determine whether the intended use of the subject device falls within the scope of the predicate device. Indications for use that specify a particular anatomical site, but do not imply diagnosis or therapy of a specific disease entity, typically fall within the scope of the general intended use for the purposes of determining substantial equivalence. When the decision-making criteria from the guidance are applied, the intended use comparison between the subject and predicate devices supports equivalence. In regards to risk, the specific use of the subject device does not introduce new risks not normally associated with endometrial sampling procedures. Furthermore, the proximal fallopian tube is housed within the uterine wall, so it is contiguous with the uterus. Therefore, the collection of samples from the proximal fallopian tube compared to the uterus does not represent a new intended use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The mechanism of action of the subject device and the predicate device is similar in that both devices extract samples from the reproductive tract by scraping against the tissue of the target anatomy. The devices are also similar in that they consist of a handle, cannula/catheter body, and, most distally, a portion that collects the sample. For all devices, this distal portion is actuated by a mechanism on the handle and a hysteroscopic view is required.

For the subject device and predicate devices, the handle is meant to 1) provide an ergonomic way of gripping the device under hysteroscopic visualization, and 2) to actuate the distal portion of the device, which then collects the sample. The cannula/catheter body of the devices is meant to provide the device stability and reach as it is placed through the working channel of the hysteroscope.

The most pertinent technological assessment is the distal end of the predicate and subject devices; specifically, the portion of the device meant to collect the sample. The primary difference between the subject and predicate devices is that the subject device uses a balloon to achieve access to the fallopian tube and to collect cells, while the U-Scope device scrapes against the uterine wall with a curette. However, the technological characteristics of the subject device do not introduce new risks when compared to the uterine sampling mechanism of the predicate device. For the subject device, wrinkles in the balloon that form as the balloon deflates create multiple edges in order to collect samples. These edges work in a manner similar to the edges of the curette of the U-Scope predicate device. Therefore, the above technological differences do not raise different questions of safety or effectiveness, as the risks associated with using the subject and predicate devices (i.e., uterine

perforation) are the same.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

- Cytotoxicity
- Vaginal irritation
- Sensitization

Mechanical testing

- Dimensional (sample size of n=15 was used for each test)
- Tensile strength of balloon, catheter, and shaft components (sample size of n=15 was used for each test)
- Simulated use testing in a uterine model, including compatibility with inflation device, compatibility with hysteroscope, and ability to access proximal fallopian tube (sample size of n=29 was used)
- Balloon inflation pressure (sample size of n=29 was used)
- Device deployment (sample size of n=15 was used)

Shelf Life Testing

Accelerated aging testing was conducted on the subject device to substantiate a shelf life of one year. The shelf life study was performed following sterilization in the original packaging. The following device specifications were evaluated in the accelerated aging study to demonstrate the subject device maintains its specifications throughout the duration of its shelf life:

- Seal integrity (visual assessment)
- Pouch leakage
- Seal strength
- Device dimensions
- Inflation pressure
- Inflated balloon dimensions
- Tensile strength (balloon, catheter, and shaft components)

Human factors and usability testing

- Physician feedback on handle ergonomics, drive wheel ergonomics, hysteroscopic visibility of balloon deployment, and ability to follow IFU
- A sample size of 3 to 7 physicians per parameter was used

Clinical testing

A prospective, single-arm clinical study was conducted to demonstrate the safety and effectiveness of the subject device in navigating the proximal fallopian tube and obtaining cell samples. A total of 40 women (80 fallopian tubes), previously scheduled to undergo a tubal ligation, were enrolled in the study. The following performance characteristics were evaluated in the study:

- Safety
- Device Performance
- Ability of device to access target anatomy
- Ability of the device to collect samples
- Ability to obtain samples that are adequate for cytological evaluation

The results demonstrated that the subject device was successfully able to navigate the fallopian tubes (75/80 successful) and collect adequate cell samples for cytology (adequate samples in 71/75 of accessible tubes). A single fallopian tube perforation, requiring no further medical intervention, was noted in one subject. Pre-existing proximal tubal occlusion was confirmed in this subject.

VIII. CONCLUSION

The bench and clinical performance data provided in support of the 510(k) confirm that the subject device is as safe and effective and substantially equivalent to the predicate device.