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

June 9, 2016

nVision Medical Corporation
% Cindy Domecus
Principal
Domecus Consulting Services LLC
1171 Barroilhet Drive
Hillsbrough, CA 94010

Re: K160510
Trade/Device Name: Mako 7
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: Class II
Product Code: HIH
Dated: May 10, 2016
Received: May 13, 2016

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,

Joyce M. Whang -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160510

Device Name
MAKO 7

Indications for Use *(Describe)*
The MAKO 7 is a hysteroscope accessory, placed through the working channel of a hysteroscope to obtain samples from the 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 31, 2016

II. DEVICE

Name of Device:	MAKO 7
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
K151275, nVision Medical Corporation	MAKO Device	MAKO 2.5

IV. DEVICE DESCRIPTION

The MAKO 7 is a hysteroscope accessory intended to collect cell samples from the 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 7 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 fallopian tube and cells are collected on its surface.

The MAKO 7 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 7 is a hysteroscope accessory, placed through the working channel of a hysteroscope to obtain samples from the fallopian tube for cytological evaluation.

The *indications for use* differ from that of the predicate, in that the indication for use for the subject device refers to the collection of samples from the fallopian tube instead of the proximal fallopian tube only. This difference does not represent a new intended use, since 1) device use is in the same anatomical structure – the fallopian tube, and 2) the difference in location *within* the fallopian tube does not alter the general purpose of the device to collect cells for cytological evaluation. As described in FDA's July 2014 guidance regarding evaluating substantial equivalence, the proposed indication is a "tool type" indication, which is not affected by the change in location within the fallopian tube.

Also, reference to device use in the fallopian tube does not raise different questions of safety and effectiveness as compared to use within the proximal portion of the fallopian tube.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The mechanism of action and principles of operation of the subject device and the predicate device are identical. Both devices use an identical handle, catheter body, and, most distally, a balloon that collects the sample. For both devices, this distal portion is actuated by a drive wheel on the handle and a hysteroscopic view is required.

There is only one difference in design between the predicate device and the subject device. This difference is that the balloon of the subject device extends 7cm into the fallopian tube while the balloon of the predicate device extends 2.5cm into the fallopian tube.

Since the subject and predicate devices collect cells by the same mechanism and in the same anatomical structure, and because the handle body, catheter body, and cell collection portion are the same, the subject device does not raise different questions of safety or effectiveness. There are also no new risks for collection of cells in the fallopian tube as compared to cell collection in the proximal fallopian tube. Indeed, in a clinical study of the subject device, no adverse events were reported.

VII. PERFORMANCE DATA

Nonclinical and clinical testing included the following:

Mechanical testing

- Dimensional (sample size of n=15 was used for each test)
- Deployment (sample size of n=15 was used for each test)
- Inflation Pressure (sample size of n=15 for each test)

Ergonomics

- Physician feedback on MAKO 7 confirmed handle ergonomics, drive wheel ergonomics, hysteroscopic visibility of balloon deployment, and ability to follow the IFU.
- A sample size of 3 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 fallopian tube and obtaining cell samples. The MAKO 7 was evaluated in 40 subjects (80 fallopian tubes) who were already scheduled to undergo a laparoscopic tubal ligation.

Study endpoints included 1) ability of the device to navigate the fallopian tube, 2) ability of the device to collect a sample adequate for cytological evaluation, and 3) adverse events. Access was achieved in 71/80 (89%) fallopian tubes. The remaining 9 tubes were determined to have pre-existing tubal occlusion, as determined by methylene blue dye injection (in two of the tubes not initially accessed a second access and navigation was successful after incidental clearing of tubal blockage after methylene blue dye injection).

The study pathologist determined that 70/71 (99 %) of the samples were adequate for cytological evaluation.

There were no device-related adverse events reported.

VIII. CONCLUSION

The bench and clinical performance data provided in support of the 510(k) confirm that the MAKO 7 subject device is as safe and effective and substantially equivalent to the MAKO 2.5 predicate device.