May 21, 2019

Boston Scientific Corporation
Ibhina Sherchan
Principal Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, MA 01752

Re: K182975
Trade/Device Name: MAKO 7
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope And Accessories
Regulatory Class: Class II
Product Code: HIH
Dated: April 10, 2019
Received: April 11, 2019

Dear Ibhina Sherchan:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Sharon M. Andrews
Assistant Division Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*
K182975

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.

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

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510(k) Summary for MAKO 7

A. Date Prepared
October 24, 2018

B. Submitter
Boston Scientific Corporation
Urology and Pelvic Health Division
100 Boston Scientific Way
Marlborough, MA 01752

C. Contact
Primary Contact:
Ibhina Sherchan
Regulatory Affairs Specialist
Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Tel: (508) 683-4215
Fax: (508) 683-5041
Email: Ibhina.Sherchan@bsci.com

Secondary Contact:
Lisa Sullivan
Director, Regulatory Affairs
Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Tel: (508) 683-4745
Fax: (508) 683-5041
Email: Lisa.Sullivan@bsci.com

D. Device Name

Trade name:	MAKO 7
Common/usual name:	Hysteroscope Accessory
Classification Name:	HIH – Hysteroscope and accessories Obstetrics/Gynecology 21 CFR 884.1690, Class II

E. Predicate Device

Trade name:	MAKO 7
Common/usual name:	Hysteroscope Accessory

Classification Name:	HIH – Hysteroscope and accessories Obstetrics/Gynecology 21 CFR 884.1690, Class II
510(k) number:	K160510

The predicate device has not been subject to a design related recall.

F. 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 catheter shaft has 3 markers to facilitate ease of use: the distal marker at the tip of the device, the retraction marker in the middle of the shaft, and the preparation (prep) marker near the proximal end. The handle includes a drive wheel and a luer that attaches to a commercially available inflation device via a 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).

G. Intended/Indications for Use

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 subject and predicate device have identical Indications for Use.

H. 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, balloon length, 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. The proposed MAKO 7 device has the same technical characteristics as its predicate, the currently cleared MAKO 7 (K160510).

I. Performance Data

No performance testing is required to evaluate the update of the Instructions for Use (IFU) to modify a warning that was previously listed and make an update to the directions for use section related to the updated warning. Performance testing

for bending (kink resistance), pulling (tensile testing), balloon extension length and presence of leaks submitted for currently cleared MAKO 7 (K160510) is applicable to the subject device.

Clinical performance data which demonstrated ability to navigate the target anatomy and obtain a sample sufficient for cytological evaluation submitted for currently cleared MAKO 7 (K160510) is applicable to the subject device.

J. Conclusion

The information provided in this submission demonstrates that the proposed MAKO 7 device is substantially equivalent to the predicate device MAKO 7, cleared in K160510.