October 1, 2020

Medacta International SA
Chris Lussier
Senior Director, Quality and Regulatory
Medacta USA
3973 Delp Street
Memphis, Tennessee 38118

Re: K200067
Trade/Device Name: MectaScope System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: September 1, 2020
Received: September 3, 2020

Dear Chris Lussier:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Pooja Panigrahi -S

for

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic 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)*

K200067

Device Name
MectaScope System

Indications for Use *(Describe)*
MectaScope System is used to examine human joints such as knee and shoulder from the inside during arthroscopic diagnostic procedures, providing surgeons with magnified images on a monitor.

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

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Contact Person: Stefano Baj, Regulatory Affairs and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Senior Director, Quality and Regulatory, Medacta USA
Date Prepared: January 13, 2020
Date Revised: September 29, 2020

II. Device

Device Proprietary Name:	MectaScope System
Common or Usual Name:	Arthroscope
Classification Name:	Arthroscope
Product Codes:	HRX
Regulation Number:	21 CFR 888.1100
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following device:

- Arthroscopic Telescopes, K943052, Karl Storz Endoscopy

IV. Reference Device

- KSEA Large Joint Arthroscopy Set, K963524, Karl Storz Endoscopy

V. Device Description

The MectaScope System is comprised of rigid scopes use to examine joints, a sheath used to access the surgical site, and obturators to facilitate the initial access of the sheath into the joint cavity in preparation for arthroscopic procedures.

The rigid scopes, manufactured primarily from stainless steel, provide a circular field of view and are available in two (2) different directions of view, 30° and 70°. The sheath, manufactured from stainless steel and EPDM, is introduced into the joint using the obturators and maintains a stable portal during the arthroscopic procedure. The obturators, manufactured with stainless steel and

EPDM, are provided with or without a handle; the obturator with a handle is compatible with a Ø 1.5 mm k-wire. The MectaScope System components are provided non-sterile and are reusable.

The MectaScope scopes are designed to be used with legally marketed camera and control units and are connected to legally marketed available light-guide cables via the light connector (designed in accordance with ISO 18339). Manufacturer specific light guide adapters are provided with the MectaScope System including adapters for Olympus/Storz, Richard Wolf, and ACMI light guide cables.

VI. Indications for Use

MectaScope System is used to examine human joints such as knee and shoulder from the inside during arthroscopic diagnostic procedures, providing surgeons with magnified images on a monitor.

VII. Comparison of Technological Characteristics

The MectaScope System and the predicate device share the following characteristics:

- arthroscope working length, diameter, field of view, and direction of view;
- sheath design;
- eyepiece design;
- materials of construction; and
- connection to legally marketed camera systems and light guide cables.

The MectaScope System and the predicate devices are technologically different with respect to the design of connections between system components, camera, and fiber optic cable, as well as sheath and obturator design.

A comparison of key technological features between the subject and predicate device is provided in the table below.

	MectaScope System	**Arthroscopic Telescopes (K943052)**
Arthroscope		
Type of scope	Rigid	Rigid
Outer diameter	4 mm	4 mm
Field of view	circular	circular
Direction of view	30° and 70°	30° and 70°
Reusable	Yes	Yes

Discussion

Although slight differences in design with respect to connections and obturator design exist, these differences do not raise different questions of safety and effectiveness as the products utilizing the

same fundamental scientific technology. Design verification and validation testing was undertaken and demonstrates that the subject device performs to specification and as intended.

VIII. Performance Data

Testing was conducted according to written protocols with acceptance criteria that were based on standards. The following mechanical studies were performed on worst-case device configurations in support of a substantial equivalence determination:

Comparative study

- Design Validation Report, Scope and Sheath – KARL STORZ Arthroscope Sheath;
    - comparison of fluid passage (volume unit per time) with the MectaScope – Rotating Sheath and the KARLSTORZ Arthroscope Sheath,
      utilizing a rotating spigot plane

Non-Clinical Studies:

- visual field and viewing direction testing per ISO 8600;
- concentricity test per ISO 18339;
- cadaver testing; and
- cleaning and sterilization validation.

IX. Conclusion

The information provided with this submission supports that the MectaScope System is substantially equivalent to the identified predicate device.

Substantial equivalence has been demonstrated through a comparison of intended use, design and technological characteristics, as well as performance evaluations.