June 25, 2021

Medi-Tate Ltd.
℅ Janice M. Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, PA 19103

Re: K210138
Trade/Device Name: iTind System
Regulation Number: 21 CFR§ 876.5510
Regulation Name: Temporarily-placed Urethral Opening System for Symptoms of Benign Prostatic Hyperplasia
Regulatory Class: II
Product Code: QKA
Dated: May 20, 2021
Received: May 20, 2021

Dear Janice M. Hogan:

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,

Mark J. Antonino, M.S.
Assistant 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: 06/30/2023
See PRA Statement below

510(k) Number *(if known)*

K210138

Device Name

iTind System

Indications for Use *(Describe)*

The iTind System is intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men age 50 and above.

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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K210138

510(k) SUMMARY

Medi-Tate Ltd.'s iTind

Submitter

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Contact Person: Lihi Liviatan

Date Prepared: June 24, 2021

Name of Device: iTind system

Regulation Name: Temporarily-placed Urethral Opening System for Symptoms of Benign Prostatic Hyperplasia

Regulation Number: 21 CFR 876.5510

Regulatory Class: II

Product Code: QKA

Predicate Device: DEN190020 – Medi-Tate's iTind

Device Description

The iTind System is a prescription temporary implantable transprostatic tissue retractor system and consists of the iTind System and a Retrieval Kit. The iTind System consists of an implant and a delivery system. The iTind implant is pre-mounted on a dedicated guide wire. The iTind implant is made of nitinol super elastic shape memory alloy (SMA), and biocompatible material widely used in the manufacture of medical devices. When in its folded configuration, the device is inserted through a sheath and deployed within the bladder neck and prostatic urethra where it assumes its expanded configuration at a maximum diameter of 33 mm and a length of 50 mm. When in expanded configuration, the struts of the iTind implant exert radial force outwardly on the bladder neck and prostatic urethra to push obstructive tissue away from the urinary path. The implant is designed to cover the entire length of the prostatic urethra, from the bladder neck to a point proximal to the external urinary sphincter. The iTind implant is left in position for 5–7 days. The device is subsequently removed using a sheath. The deployment and removal of the iTind implant should follow the Instructions For Use supplied by Medi-Tate and should only be attempted after the operator has been appropriately trained. The device is compatible with commercially available cystoscopes at least 19Fr in diameter.

Indications for Use

The iTind System is intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men age 50 and above.

Summary of Technological Characteristics

Several components of the device are being modified to use different materials of construction and to add visual markers to improve ease of use. In addition, the shelf-life was extended to 3 years. These changes do not raise different types of safety or efficacy questions.

Performance Data

- EN ISO 10993 –1: 2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, 2-258
- ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity, 2-228
- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity, 2-245
- ISO 10993-6:2016 Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation, 2-247
- ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals, 14-408
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization, 2-174
- ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity, 2-255
- EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems, 15-530
- EN ISO 11607-2:2019 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes, 15-531
- ASTM F2096-11 Standard test method for detecting gross leaks in packaging by internal pressurization - bubble test, 14-359
- ASTMF1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices, 14-497

Conclusions

The subject iTind is as safe and effective as the predicate iTind. The subject iTind has the same intended use, indications, and principles of operation and similar technological characteristics as its predicate device. The minor technological differences between the iTind and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the iTind is as safe and effective as the predicate iTind. Thus, the subject device is substantially equivalent.