August 27, 2024

Laborie Medical Technologies Corp.
Thomas Hirte
Sr. Director Regulatory Affairs
180 International Drive
Portsmouth, New Hampshire 03801

Re: K241523
Trade/Device Name: injeTAK Adjustable Tip Needle (DIS199; DIS201)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBK
Received: August 2, 2024

Dear Thomas Hirte:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 R. Kreitz -S

for 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241523

Device Name

injeTAK Adjustable Tip Needle (DIS199; DIS201)

Indications for Use *(Describe)*

The injeTAK Adjustable Tip Needles are intended to be used to deliver a variety of legally marketed drugs into tissues or structures during cystoscopic procedures. They are provided sterile for single use only.

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) #: K241523

510(k) Summary

Prepared on: 2024-08-01

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Laborie Medical Technologies Corp.
Applicant Address	180 International Drive Portsmouth NH 03801 United States
Applicant Contact Telephone	978-277-6432
Applicant Contact	Mr. Thomas Hirte
Applicant Contact Email	thirte@laborie.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	injeTAK Adjustable Tip Needle (DIS199; DIS201)
Common Name	Endoscope and accessories
Classification Name	Endoscopic Injection Needle, Gastroenterology-Urology
Regulation Number	876.1500
Product Code(s)	FBK, N/A

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K090830	injeTAK Adjustable Tip Needle	FBK

Device Description Summary

21 CFR 807.92(a)(4)

The injeTAK Adjustable Tip Needles (injeTAK Needles) are intended to be used to deliver a variety of legally marketed drugs into tissues of structures during cystoscopic procedures. They are provided sterile for single use only.
The needles will contact the bladder tissue and urine fluid in the patient. The typical injection procedure lasts 10-20 minutes; each injection spot contact lasts approximately 5 seconds but may vary slightly depending on the skill of surgeon.
The models of the injeTAK needles are used with a rigid or flexible cystoscope during cystoscopic procedures and differ in length of the needle dependent upon the type of procedure. The intended use does not vary based on the model number or difference in measurement specifications.
The injeTAK Needle comprises of a needle cannula, contrast mark, needle sheath, handle, needle length dial, hub/luer connector, lock-pin, and a seal ring located inside the handle.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The injeTAK Adjustable Tip Needles are intended to be used to deliver a variety of legally marketed drugs into tissues or structures during cystoscopic procedures. They are provided sterile for single use only.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the proposed device remain the same as the predicate device

Technological Comparison

21 CFR 807.92(a)(6)

The basic technology for the subject device and the predicate device (injeTAK Adjustable Tip Needles) is the same. The injeTAK Needle comprises of a needle cannula, contrast mark, needle sheath, handle, needle length dial, hub/luer connector, lock-pin, and a seal ring located inside the handle. The injeTAK Needles do not include software or a dispensing device (i.e., syringe). The sheath is attached to housing and the needle cannula is attached to a needle hub. Five depths are listed on the needle handle (0, 2, 3, 4, and 5), with each number corresponding to the needle tip length in millimeters. For example, when the needle lock-pin is set at the number 3, the maximum needle tip penetration depth is 3mm. There is also a black contrast mark at the distal end of the plastic sheath which provides a better view of injection spot.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-clinical tests were conducted to verify that the subject device met all design specifications. The subject device is substantially equivalent to the predicate. No clinical testing was included in this submission.

Biocompatibility:
No additional testing is required since the changes to the standards do not affect the results of the Cytotoxicity & Pyrogenic tests, Sensitization tests or Intracutaneous Reactivity tests previously conducted on the injeTAK needles. The performed biocompatibility tests show that the injeTAK needles are safe and perform as intended. The materials of all components in the device have not changed and stay as exact the same as existing G1 needles. Thus, we can conclude that the device biocompatibility will be well maintained for injeTAK G2 versions (DIS 199 & DIS 201).

Packaging:
InjeTAK Packaging Design Verification was completed on the subject device for the packaging change to provide results of the product's packaging testing against released requirements to ensure the integrity of primary packaging meets essential performance at the final point of delivery after enduring the worst-case transportation conditions.
InjeTAK Adjustable Tip Needles meet the requirements of variously corresponding international standards after the Transportation Simulation Test by functional testing, package integrity testing. All test results passed and met the acceptance criteria.

Sterilization:
The packaging change required the sterilization process to be revalidated in order to maintain the sterilization cycle parameters specified in the original cycle parameters/design. The testing performed confirms that sterilization output requirements were met.

Functional & Performance Testing:
The test was intended to verify if the device critical dimensions, function/performance meet the design specifications stated in the design files. The test results passed the acceptance criteria. Overall performance and results were positive and meet the related specifications.
The packaging material and dimension have not changes and stay as exact the same as version G1. The overall footprint and weight are equivalent. Therefore, it can be concluded that the device packaging performance and integrity will be maintained for injeTAK G2, and revalidation tests are not needed.

Accelerated Aging and Shelf Life:
No additional accelerated aged tests were needed for the G2 subject device versions (DIS199 & DIS201) of the InjeTAK Needles. Since there was no change in the material, biocompatibility, packaging, aging and/or sterilization process for the G2 needles versions, the accelerated test reports conducted on the G1predicate versions (DIS198 & DIS201) of the InjeTAK needles are applicable to the G2 versions as well.

The impact of aging (i.e. shelf life) on functionality and performance of the InjeTAK G2 subject device versions (DIS199 & DIS201) remains unchanged. The three main functions – flow rate, needles bond strength and needle leur leek test were evaluated. The essential functionality and performance of InjeTAK G2 version (DIS199 & DIS201) passed all requirements after accelerated aging and are therefore acceptable for the three year shelf life

Verification and Validation testing were performed on the InjeTAK Needles to ensure that the devices will perform as intended. All testing passed. Details are provided in the verification and validation section of this submission