



June 18, 2024

ITP Innovative Tomography Products GmbH  
Dominik Främke  
Project Manager  
Universitätsstraße 136  
Bochum, 44799  
Germany

Re: K233294

Trade/Device Name: Automatic Biopsy Needle BAM, Semi-Automatic Needle BIM  
Regulation Number: 21 CFR 876.1075  
Regulation Name: Gastroenterology-Urology Biopsy Instrument  
Regulatory Class: Class II  
Product Code: KNW  
Dated: May 21, 2024  
Received: May 21, 2024

Dear Dominik Främke:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Jessica Carr -S**

Jessica Carr, Ph.D.

Assistant Director

DHT4A: Division of General Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K233294

Device Name

Automatic Biopsy Needle - BAM

Semi-automatic Biopsy Needle - BIM

Indications for Use (Describe)

The biopsy-needle is intended for soft-tissue biopsy (such as breast, kidney, liver, prostate).

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

This 510(k) Summary is being submitted in accordance with requirements of 21CFR Section 807.92.

The assigned 510(k) Number: K233294

Date of Preparation: 06/17/2024

**Submitter** Innovative Tomography Products GmbH  
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**Contact:** Dominik Främke ( project manager)

**Device Trade Name:** Automatic Biopsy Needle – BAM  
Semi-automatic Biopsy Needle - BIM

**Common Name:** Gastroenterology-urology biopsy instrument

**Classification:** Instrument, Biopsy

**Regulation:** 876.1075

**Product Code:** KNW

**Primary Predicate:** K222462

**Device Description Summary:** The Semi-automatic Biopsy-Needle – BIM and Automatic Biopsy Needle - BAM are sterile, spring loaded, disposable percutaneous soft tissue biopsy systems. It consists of the following major components: handle, spring, cannula, stylet, trigger and spring guide. It is used to obtain multiple core biopsy samples from soft tissue such as breast, kidney, liver and prostate. The needle has to be inserted by a qualified physician under MR image guidance.

**Indications for Use:** The biopsy-needle is intended for soft-tissue biopsy (such as breast, kidney, liver, prostate).

**Indications for Use Comparison** The indications for use statement of the subject device is identical to the indications for use statement of the primary predicate device.

**Technological Comparison**

The Semi-automatic Biopsy Needle - BIM and Automatic Biopsy Needle - BAM are identical or similar in technology, design and material to the predicate device. Both devices are sterile and for single-use.

The material of the needles are identical to the predicate/reference device. Based on the same intended use and the similarities in technology, design and materials the proposed devices are substantially equivalent to their predicate/reference devices. Biocompatibility, MR-testing, sterility and packaging demonstrate the safety and effectiveness of the proposed device.

Device & Predicate Device(s):	<a href="#">K233294</a> <a href="#">Automatic (BAM)</a> <a href="#">Semi-Automatic (BIM)</a>	<a href="#">K222462 (Predicate)</a> <a href="#">Semi-Automatic (BIM)</a>
<b>General Device Characteristics</b>		
Material	Needle: Inconel 625, Nitinol Handle: ABS	Needle: Inconel 625, Nitinol Handle: ABS
Size Diameter (G)/Length (mm)/Notch (mm)	BAM/BIM Diameter: 18, 16 BAM/BIM Length: 100, 150, 175, 200 Notch: 18 (BAM), 10/18 (BIM)	Diameter: 18, 16, 14 Length: 100, 150, 200 Notch: 10/20 (BIM)
Design	BAM: Cutting is performed with an automatic gun with guillotine system; mandrin is moved automatically with the help of a spring. BIM: Cutting is performed with an automatic gun with guillotine system; mandrin is moved manually	Cutting is performed with an automatic gun with guillotine system; mandrin is moved manually.
Single Use	Yes	Yes
Cannula Covers the notch of stylet	Yes	Yes
Biopsied Tissue Sample Length (Cylindrical, Intact)	>10 mm (BAM, 18 mm notch) >10 mm (BIM, 18 mm notch) > 7 mm (BIM, 10 mm notch)  Tissue Types: Muscle, Liver, Kidney	In Muscle: ~6.72 mm for 10 mm Notch (BIM) ~11.77 for 20 mm Notch (BIM) Overall (Muscle, Liver, Apple) ~8.82 mm for 10 mm Notch (BIM) ~17.22 for 20 mm Notch (BIM)
Monitoring	MRI	MRI
Sterilization	EO	EO
Packaging	Sterile pouches made of sterilization-resistant 70 g/m <sup>2</sup> heavy-duty paper and a plastic film	Tyvek bag

**Non-Clinical Tests**

The following tests were performed to evaluate the performance of the subject device and support substantial equivalence with the predicate device.

- 1) Penetration of the needle
- 2) Shot of the needle
- 3) Quantity of the sample taken
- 4) Quality/integrity of the sample taken

## 5) MRI Safety Evaluation

For the present report different Semiautomatic Biopsy Needles - BIM and Automatic Biopsy Needles - BAM has been used. 18G and 16G biopsy needles were used. Two lengths were used: 150 mm and 200 mm. The testing was conducted after the validated EO sterilization of all devices. Therefore the tests were conducted on final finished devices.

### Description of the tests and Results

1) For the stylet perforation capacity, a biopsy needle is inserted in three different tissues (i.e., muscle, liver, kidney) according to the IFU. It is then visually tested to ensure that the stylet tip could easily and effortlessly penetrate the tissue without causing tears or lacerations to create a good entry path for the cannula. The needle is inserted in different tissues to assess the penetration capacity of the stylet tip. For all tested biopsy devices the insertion was appropriate and conducted effortlessly with no difficulties at all. The acceptance criteria were met. This demonstrates that the device works as intended.

2) To test the shot of the needle the release mechanism of the biopsy device was triggered in air as well as in the animal tissue. The test showed that the device spring has sufficient power for the cannula to cover the tip of the stylet that contains the notch completely. The tests were conducted for the 10 mm and 18 mm notch.

3) Different tissue samples were taken with biopsy devices for the 10 mm and 18 mm notch. After that the length of the collected samples was measured with a ruler. The length was written down and the results were analyzed. The results showed that the device met the acceptance criteria (e.g.,  $\geq 5$  mm for the 10 mm notch and  $\geq 9$  mm for the 18 mm notch) and the dimensions of the samples were comparable to the dimensions of the sample acquired using the predicate.

4) The taken tissue samples in test 3 are observed under video microscope. The samples were carefully observed to see if they are cylindrical, intact and abundant. This was done for both 10 mm and 18 mm notch samples. All samples were cylindrical, intact and abundant. The acceptance criteria were met. The samples collected using the subject device were comparable to the samples acquired using the predicate.

5) MRI safety evaluation was performed to develop conditions of safe use.

**Clinical Tests** Not needed.

**Conclusion** Based on the comparison and analysis above, the proposed subject device is determined to be Substantially Equivalent (SE) to the predicate device.