ITP Innovative Tomography Products GmbH
Dominik Fraemke
Project Manager
Universitaetsstr. 136
Bochum, 44799
Germany

January 20, 2023

Re: K222462
Trade/Device Name: Semi-automatic Biopsy-Needle (BIM 18/20); Semi-automatic Biopsy-Needle (BIM 18.15); Semi-automatic Biopsy-Needle (BIM 18/10);Semi-automatic Biopsy-Needle (BIM 16/20);Semi-automatic Biopsy-Needle (BIM 16/15);Semi-automatic Biopsy-Needle (BIM 16/10);Semi-automatic Biopsy-Needle (BIM 14/20);Semi-automatic Biopsy-Needle (BIM 14/15);Semi-automatic Biopsy-Needle (BIM 14/10)
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: October 24, 2022
Received: October 24, 2022

Dear Dominik Fraemke:

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,

Colin K. Chen -S

for

Long Chen, 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

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.*

Submission Number *(if known)*

Device Name

Semi-automatic Biopsy-Needle (BIM 18/20);
Semi-automatic Biopsy-Needle (BIM 18/15);
Semi-automatic Biopsy-Needle (BIM 18/10);
Semi-automatic Biopsy-Needle (BIM 16/20);
Semi-automatic Biopsy-Needle (BIM 16/15);
Semi-automatic Biopsy-Needle (BIM 16/10);
Semi-automatic Biopsy-Needle (BIM 14/20);
Semi-automatic Biopsy-Needle (BIM 14/15);
Semi-automatic Biopsy-Needle (BIM 14/10)

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.**

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

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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510(k)#: K222462

# 510(k) Summary

Prepared on: 2022-12-22

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
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## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | Semi-automatic Biopsy-Needle (BIM 18/20);<br>Semi-automatic Biopsy-Needle (BIM 18/15);<br>Semi-automatic Biopsy-Needle (BIM 18/10);<br>Semi-automatic Biopsy-Needle (BIM 16/20);<br>Semi-automatic Biopsy-Needle (BIM 16/15);<br>Semi-automatic Biopsy-Needle (BIM 16/10);<br>Semi-automatic Biopsy-Needle (BIM 14/20);<br>Semi-automatic Biopsy-Needle (BIM 14/15);<br>Semi-automatic Biopsy-Needle (BIM 14/10) |
| Common Name | Gastroenterology-urology biopsy instrument |
| Classification Name | Instrument, Biopsy |
| Regulation Number | 876.1075 |
| Product Code | KNW |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K130616 | Semi-Automatic Biopsy Needle | KNW |

## Device Description Summary

21 CFR 807.92(a)(4)

The semiautomatic Biopsy needle – BIM is a sterile, spring loaded, disposable percutaneous soft tissue biopsy system. It consists of the following major components: handle, spring, cannula, stylet, trigger and spring guide. It is used to obtain multiple core biopsy samples

following major components: handle, spring, cannula, stylet, trigger and spring guard. It is used to obtain multiple core biopsy samples from soft tissue such as the kidney, prostate, liver, lymph nodes, breast etc. The needle has to be inserted by a qualified physician under MR image guidance.

## Intended Use/Indications for Use 21 CFR 807.92(a)(5)

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

## Indications for Use Comparison 21 CFR 807.92(a)(5)

The proposed devices are working equivalently to the predicate device. They are all intended to obtain diagnostic samples of soft tissue for histological examination during a percutaneaous biopsy procedure. They differ only in optical design aspects. In addition the proposed device is MR-compatible.

## Technological Comparison 21 CFR 807.92(a)(6)

The BIM is identical or similar in technology, design and material to the predicate device. Both devices are sterile and for single-use. The only difference between the two devices are the materials of the needles as well as optical design aspects. 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.

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

The purpose of the tests is to evaluate:
1) the penetration of the needle
2) The shot of the needle
3) The quantity of the sample taken
4) The quality/integrity of the sample taken
5) MR tests for artificat
6) Heating and induction test
7) Biocompatibility

For the present report different Semiautomatic Biopsy Needles BIM has been used. The 5 samples have been manufactured in 5 different lots. 14G, 16G and 18G biopsy needles were used. The lengths ranged from 100 mm, 150 mm and 200 mm. The testing was conducted after the validated EO sterilization of all devices. Therefore the tests were conducted on final devices

Description of the tests
1) For the stylet perforation capacity, a biopsy needle is inserted in three different tissues (animal tissue and apples) 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.
2) To test the shot of the needle the release mechanism of the biopsy device were triggered in the air as well as in the animal tissue. If the device works well, the cannula would cover the tip of the stylet that contains the notch completely. With this you can test if the spring has enough power to push the cannula over the notch to cut tissue. This was conducted for the 10 mm and 20 mm notch.
3) Different tissue samples were taken with biopsy devices for the 10 mm and 20 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.
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 also done for 10 mm and 20 mm notch samples.
5&6) Furthermore MR-compatibility tests were conducted.
For the tests we used similar needles that use the same materials as the biopsy devices and tested them under a 3T and 1.5T MRI-System. The needle is clearly visible under MR-guidance without any major artifacts. Furthermore no heating or induction occured in any unit.
7) Biocompatibility tests for Cytotoxicity, Sensitization, Irritation, Acute Systemice Toxicity and Pyrogenicty were conducted.

1.Needle penetration capacity

For all tested biopsy devices the insertion was optimal and conducted effortlessly with no difficulties at all. The acceptance criteria were met. This demonstrates that the devices works for penetration and is safe.

2.Shot of the needle.

For all tested biopsy device the cannula covers the notch completely. This is the case for botch notch sizes (10 mm and 20 mm). From this

For untested biopsy device the cannula covers the notch completely. This is the case for both notch sizes (10 mm and 20 mm). From this it can be concluded that the spring is strong enough. The acceptance criteria were met and the device works and is safe.

3.Quantity of the collected samples

Each sample for the liver and apple equals the notch size. For muscle tissue taken with the 10 mm notch the average length is 6.72 mm and for 20 mm notch 11.77 mm. Every sample was larger than the acceptance criteria of 5 mm and 10 mm. Therefore the criteria is met. The average sample size over all tissues is 8.82 mm for the 10 mm notch and 17.22 for the 20 mm notch. The device is therefore effective to take proper samples.

4.Quality/integrity of the collected samples

All samples are cylindrical, intact and abundant. The acceptance criteria were met.
Because of this the device is effective and safe.

Based on the performed tests the proposed device is as safe and as effective as the predicate device. Furthermore the average sample size of the collected tissue is larger for the proposed device.
Proposed device: 10 mm notch: 8.82 mm samples, 20 mm notch: 17.22 mm samples
Predicate device: 10 mm notch 7 cm samples, 20 mm notch: 13 mm samples

5&6.
Based on the MR-tests the device is MR-compatible. The needle didn't show any major artificats and is cleary visible especially compared to the needle with stainless steel. In addition no heating or induction orccured during these tests.

7. Biocompatibility were proofen with the conducted tests.

Conclusion:
The Semi-automatic Biopsy-Needle functions as intended. The results drawn from the non-clinical tests as well as the literature presented in this 510(k) submission demonstrate the proposed device is as safe, effective and performs as well as the legally marketed predicate device. The proposed device has a similiar intended use and similiar key technological and design characteristics. The MR-compatbility were proven with MR-tests and the different needle material is also biocompatibility. Therefore the proposed device is substantially equivalent to the predicate device.