February 2, 2022

TeesuVac ApS
Mr. John Hvidkjaer
CEO
Agern Alle 3
2970 Hoersholm
Denmark

Re: K212079
Trade/Device Name: TeesuVac Breast Biopsy Device Mark 1
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: December 30, 2021
Received: January 5, 2022

Dear Mr. Hvidkjaer:

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,

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.

510(k) Number *(if known)*
K212079

Device Name
TeesuVac Breast Biopsy Device Mark 1

Indications for Use *(Describe)*
The TeesuVac Breast Biopsy Device Mark 1 is indicated to obtain percutaneous core biopsy specimens from soft tissue, and tumors of the breast. This product is intended for diagnostic use only, NOT therapeutic therapy. The instrument is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removing the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g., malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

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 of Safety and Effectiveness 21 CFR 807.92
TeesuVac Breast Biopsy Device Mark 1 (k212079)

Traditional 510k

Date Summary Prepared
February 1st, 2022

Submitter's Identification
TeesuVac ApS
Agern Allé 3
2970 Hoersholm
Denmark
Phone: +45 6155 8399
Telefax: N/A
Email: jhv@teesuvac.com
Website: www.teesuvac.com

Contact
Mr. John Hvidkjaer
CEO
TeesuVac ApS
Agern Allé 3
2970 Hoersholm
Denmark
Phone: +45 6155 8399
Telefax: N/A

Device

Common Name: Vacuum-Assisted Biopsy Device

Regulatory Class: II

Classification: 21 CFR 876.1075 – Gastroenterology-urology biopsy instrument

Product Code: KNW

Predicate Device

Predicate #1:

Trade/Proprietary Name: Bard

Max-Core Disposable Core Biopsy Instrument

Premarket Notification: k133948

Manufacturer: Bard Peripheral Vascular, Inc

TeesuVac Breast Biopsy Device Mark 1 is a sterile, tetherless vacuum-assisted handheld biopsy device intended to obtain percutaneous core biopsy specimens from soft tissue and tumors of the breast with ultrasound guidance. TeesuVac Breast Biopsy Device Mark 1 is intended for biopsy and diagnosis only. The device is battery-driven and for single-patient use. An unsterilized Battery Pack that comes with the biopsy device is applied using the sterile Battery Clip, stored in the tray containing the biopsy device. The device is fitted with a 14G needle set to obtain specimens from soft tissue and tumors. The device is for professional users only. The tissue harvested by TeesuVac Breast Biopsy Device Mark 1 is intended for diagnostic use only.

The cannula needle consists of two hollow cannulas, an inner cannula with a specimen chamber, and a sharp outer cutting cannula that extends at high speeds over the aperture to acquire targeted tissue specimens. During the shot, a vacuum pulls the tissue into the chamber, followed by moving the outer cutting cannula forward over the specimen chamber to cut the tissue and collect the specimen in the specimen chamber. The TeesuVac Breast Biopsy Device Mark 1 has two buttons: the Slider for loading and the Sampling button to perform the biopsy procedure.

Indications for use

The TeesuVac Breast Biopsy Device Mark 1 is indicated to obtain percutaneous core biopsy specimens from soft tissue and tumors of the breast. This product is intended for diagnostic use only, NOT therapeutic therapy. The instrument is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removing the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g., malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be

examined for completeness of removal using standard surgical procedures.

Summary of the technological characteristics of the device compared to the predicate device

TeesuVac Breast Biopsy Device Mark 1 is identical in terms of indications for use and the technology to the Bard Max-Core Disposable Core Biopsy Instrument manufactured by Bard Peripheral Vascular, Inc, whose predicate device is currently in commercial distribution and US-FDA cleared under k133948.

Table 1 below summarizes the technological characteristics of TeesuVac Breast Biopsy Device Mark 1 vs. the predicate device.

#	Attribute	**PREDICATE DEVICE** Bard Max-Core (K133948)	**SUBJECT DEVICE** TeesuVac Breast Biopsy Device Mark 1 (k212079)	Evaluation
1	Device Type	Biopsy Instrument	**Biopsy Instrument**	*Same as Bard Max-Core*
2	Regulation Number	21 CFR 876.1075	**21 CFR 876.1075**	*Same as Bard Max-Core*
3	Product code	KNW	**KNW**	*Same as Bard Max-Core*
4	Indication for Use	The Core needle biopsy device is intended for use in obtaining biopsies from soft tissues such as the liver, kidney, prostate, spleen, lymph nodes, and various soft tissue tumors. It is not intended for use in bone.	**The TeesuVac Breast Biopsy Device Mark 1 is indicated to obtain percutaneous core biopsy specimens from soft tissue and tumors of the breast. This product is intended for diagnostic use only, NOT therapeutic therapy. The instrument is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.** **The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removing the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g., malignancy). When the sampled abnormality is not histologically benign, the tissue margins must be**	*Similar to Bard Max-Core. However, Bard Max-Core has a broader indication for use*

#	Attribute	**PREDICATE DEVICE** Bard Max-Core (K133948)	**SUBJECT DEVICE** TeesuVac Breast Biopsy Device Mark 1 (k212079)	**Evaluation**
			examined for completeness of removal using standard surgical procedures.	
5	Patient Population	Individuals requiring biopsy for a sampling of soft tissue abnormalities	**Any patient population requiring the harvest of cellular material**	*Similar to Bard Max-Core but has no impact on safety*
6	Disposable	Single-use	**Single-use**	*Same as Bard Max-Core*
7	SAL level	SAL > 10^{-6}	**SAL > 10^{-6}**	*Same as Bard Max-Core*
8	Sterilization method	Ethylene Oxide	**Gamma**	*Similar to Bard Max-Core, but have no impact on safety*
9	Visualization Techniques	X-ray, ultrasound, CT, etc.	**Ultrasound Imaging**	*Similar Bard Max-Core. However, Bard Max-Core can be applied to several visualizations' techniques*
10	Principle of Operation	Prepare the site as required. Insert the tip of the needle and advance to the desired location. For ease of insertion, puncture the skin with a scalpel at the entry site.	**Make a small incision or puncture the skin with a scalpel. Using ultrasound guidance, insert the needle through the incision, and position the tip to the appropriate depth.**	*Similar to Bard Max-Core but have no impact on safety*
11	Materials	A single-use device composed primarily of plastics and stainless steel	**A single-use device composed primarily of plastics and stainless steel**	*Same as Bard Max-Core*
12	Patient contacting materials	Stainless steel needle (and rarely the plastic handle)	**Stainless steel needle** (and rarely the plastic handle)	*Same as Bard Max-Core*
13	Mechanical principle	A self-contained handheld mechanical spring-loaded biopsy device	**A self-contained handheld electromechanical vacuum-assisted biopsy device**	*Similar to Max-Core. Max-Core is not electromechanical, but it has no impact on safety*
14	Number of tissue samples	Single sample per puncture	**Single sample per puncture**	*Same as Bard Max-Core*
15	Mechanism of action	The inner tube moves forward The outer tube moves forward	**Outer tube retracts** **The outer tube moves forward**	*Similar to Bard Max-Core but have no impact on safety*
16	Mode of action	Fast-moving outer tube	**Fast-moving outer tube**	*Same as Bard Max-Core*

#	Attribute	**PREDICATE DEVICE** Bard Max-Core (K133948)	**SUBJECT DEVICE** TeesuVac Breast Biopsy Device Mark 1 (k212079)	**Evaluation**
17	Needle Design	• Separate Coaxial Cannula • Hollow outer cutting cannula. • Hollow notched inner needle/bevel tipped, no transport of tissue. • Aspiration via inner needle	• **Separated Coaxial Cannula** • **Hollow outer cutting cannula** • **Notched inner needle/trocar tipped, no transport of tissue** • **Aspiration via inner needle**	*Same as Bard Max-Core*
18	Needle diameter/gauge	14G	**14G**	*Same as Bard Max-|Core*
19	Number of samples	Single sample per puncture	**Single sample per puncture**	*Same as Bard Max-Core*
20	Sample weight	10 mg (Pig breast)	**14 mg (Pig Breast)**	*Similar to Bard Max-Core*
21	Sample Length	8,35 mm (Pig breast)	**9,04 mm (Pig breast)**	*Similar to Bard Max-Core but have no impact on safety*
22	Number of segments in samples	Minimum 1,2 segments, Maximum 2,1 segments	**Minimum 1 segment, Maximum 2,1 segments**	*Similar to Bard Max-Core but have no impact on safety*
23	Sample Quality score	4,86	**7,71**	*Similar to Bard Max-Core but have no impact on safety*
24	Durability	≥ 5 shots Intact needle tip	**≥ 5 shots** **Intact needle tip**	*Same as Bard Max-Core*
25	Duration of the sample cut	< 1 second	**< 1 second**	*Same as Bard Max-Core*
26	Firing Distance (Needle Advancement (piercing) or no Advancement (Steady cut))	22mm (piercing)	**21,5 mm** (Steady cut)	*Similar to Bard Max-Core but have no impact on safety*
27	Power source	NA (Mechanical only)	**Low Voltage VDC motor**	*Similar to Bard Max-Core but have no impact on safety*
28	Energy Used/Delivered	NA (Mechanical, delivered by a manual operation)	**Direct Current from Battery**	*Similar to Max-Core but have no impact on safety*
29	Stroke/Travel length outer tube	22 mm	**21,5 mm**	*Similar to Bard Max-Core but have no impact on safety*

#	Attribute	PREDICATE DEVICE Bard Max-Core (K133948)	SUBJECT DEVICE TeesuVac Breast Biopsy Device Mark 1 (k212079)	Evaluation
30	Penetration (Initial Penetration Force)	1,0 N	**0,8 N**	*Similar to Bard Max-Core but have no impact on safety*
31	Penetration Force - Pear (depth of 12,5 mm)	5,6 N	**6,1 N**	*Similar to Bard Max-Core but have no impact on safety*
32	Bending load (Deflection at 40 N <0,4 mm)	0,19 mm	**0,29 mm**	*Similar to Bard Max-Core but have no impact on safety*
33	Probe tip welding strength Resistance to 100N	Yes	**Yes**	*Same as Bard Max-Core*
34	Operated by either hand	Right or left	**Right or left**	*Same as Bard Max-Core*
35	Packaging materials	PET, and Tyvek	**PET, Tyvek, and LDPE**	*Similar to Bard Max-Core but has no impact on safety*

Similarities between the TeesuVac Breast Biopsy Device Mark 1 and the predicate device(s):

- Same Device type, Regulation number, and Product code
- Similar indications for use
- Similar Patient population
- Similar fundamental scientific technology
- Similar operating principle
- Single-use device
- The same number of samples per incision
- Similar needle material, design, and gauge
- Similar weight mass of the sample size
- Similar length
- A similar number of segments
- Similar Sample Quality score
- The same durability and needle tip intact
- Similar penetration force, initially and in-depth
- Same packaging materials
- Similar sterility assurance level and method of sterilization

The only directly patient contacting material is the needle, and all the needles are made of Stainless steel AISI 304, which is the same material.

Differences between the TeesuVac Breast Biopsy Device Mark 1 and the predicate device:

The mechanical principle of the Bard Max-Core is a self-contained handheld mechanical spring-loaded biopsy device. The TeesuVac Breast Biopsy Device Mark 1 is a self-contained handheld electromechanical spring-loaded vacuum-assisted biopsy device energized by a

motor powered by low voltage batteries (power supply). However, both the TeesuVac Breast Biopsy Device Mark 1 and the Bard Max-Core are essentially performing the sample harvesting utilizing springs that have been compressed. Whether the springs have been compressed by manual force or electromechanically driven force is insignificant. It is still similar regarding the sample, and thus no difference concerning safety and effectiveness.

The mechanism of action and mode of action of the TeesuVac Breast Biopsy Device Mark 1 is that the outer tube retracts to open the tissue chamber and subsequently moves forward to harvest the sample. The Bard Max-Core has a piercing shot where the inner core moves forward to open the tissue chamber, and the outer tube subsequently moves forward to harvest the sample. However, the TeesuVac Breast Biopsy Device Mark 1 is additionally vacuum-assisted. The Bard Max-Core and TeesuVac Breast Biopsy Device Mark 1 have fast-moving outer tubes that harvest the sample. The Bard Max-Core and TeesuVac Breast Biopsy Device Mark 1 are therefore comparable in their cutting method. The tissue samples' weight is comparable to that of the predicate device. There are no differences concerning vacuum-assisted and core needle devices regarding safety and effectiveness.

Testing Summary:

The TeesuVac Breast Biopsy Device Mark 1 was evaluated in the following non-clinical studies: in-vitro device performance, electrical & product safety (IEC 60601-1, 60601-1-2), sterilization, biocompatibility, predicate device comparison, and simulated use testing.

Conclusion

The proposed TeesuVac Breast Biopsy Device Mark 1 (k212079) is substantially equivalent to the predicate device Bard Max-Core Disposable Core Biopsy Instrument (k133948).

The differences between the proposed and predicate devices do not impact the safety and effectiveness of the proposed device. Performance testing supports that the proposed device is substantially equivalent to the legally marketed predicate device.