February 27, 2025

Xaga Surgical
Anders Grim
QA Manager
Alnarpsgatan 81
Helsingborg, Scan SE-256 67
SWEDEN

Re: K242128
Trade/Device Name: Forsvall biopsy needle system for prostate biopsy
(Forsvall biopsy gun and Forsvall biopsy needle)
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: II
Product Code: KNW
Dated: July 19, 2024
Received: January 31, 2025

Dear Anders Grim:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 J. Antonino -S

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)*

K242128

Device Name

Forsvall biopsy needle system for prostate biopsy (Forsvall biopsy gun and Forsvall biopsy needle)

Indications for Use *(Describe)*

The Forsvall biopsy needle is intended to collect histological biopsy samples from soft tissue intended for clinical examination. The Forsvall biopsy needle is part of the Forsvall biopsy needle system for prostate biopsy and shall be used together with the Forsvall biopsy gun.
The Forsvall biopsy gun is intended to be used by medical professionals, together with the Forsvall biopsy needle, on male patients to obtain soft tissue samples. The Forsvall biopsy gun is part of the Forsvall biopsy needle system for prostate biopsy.

The Forsvall biopsy needle system for prostate biopsy is indicated whenever there is a need to obtain prostate biopsy samples.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) #: K242128

510(k) Summary

Prepared on: 2025-02-26

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Xaga Surgical
Applicant Address	Alnarpsgatan 81 Helsingborg Scania SE-256 67 Sweden
Applicant Contact Telephone	+46707109969
Applicant Contact	Mr. Anders Grim
Applicant Contact Email	andersgrim@xagasurgical.com
Correspondent Name	Stravus AB
Correspondent Address	Iliongränden 320 Lund Scania 22471 Sweden
Correspondent Contact Telephone	+46708960161
Correspondent Contact	Mr. Michael Lundh
Correspondent Contact Email	michaellundh@xagasurgical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Forsvall biopsy needle system for prostate biopsy (Forsvall biopsy gun and Forsvall biopsy needle)
Common Name	Gastroenterology-urology biopsy instrument
Classification Name	Instrument, Biopsy
Regulation Number	876.1075
Product Code(s)	KNW, KNW (CLASS 2) - INSTRUMENT, BIOPSY

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K162588	Möller Medical Biopsy Needles and Systems	KNW

Device Description Summary

21 CFR 807.92(a)(4)

The Forsvall biopsy needle system for prostate biopsy consists of two items: the Forsvall biopsy needle and the Forsvall biopsy gun. The Forsvall biopsy needle is intended for use with the Forsvall biopsy gun. The Forsvall biopsy gun is reusable and the biopsy needle is single use. The Forsvall biopsy system uses a spring loaded gun that mediates a biopsy needle with a side notch used to obtain tissue samples. The biopsy gun is made of metal and hard plastic and the 16/18 gauge 10/15/20/25 cm biopsy needle is made of stainless medical grade steel.

By pulling a handle on the Forsvall biopsy gun, the front wagon therein is tensioned and connected to the outer tube in the Forsvall biopsy needle. When tensioning the front wagon, the load pin also moves along a guide curve. When the front wagon is in its loaded position, the load pin has moved the front needle bracket a small distance backwards in the Forsvall biopsy gun.

The handle is pulled a second time to tension the rear wagon that is connected to the needle in the Forsvall biopsy needle. A tension is created between the outer tube and the needle in order to force closing of the Forsvall biopsy needle. The purpose is to prevent an interstice from arising in order to prevent accumulation of bacteria.

The Forsvall biopsy gun is fired by pushing the trigger, which causes the rear wagon to move forward followed by movement of the front wagon. This results in the inner part of the Forsvall biopsy needle is forced forward, followed by forward movement of the outer tube. When the Forsvall biopsy gun is fired, the load pin moves the outer tube the final millimeter in order to achieve a soft closing mechanism. On the Forsvall biopsy needle, the outer tube thus stops against the needle head and it is forced closed.

The Forsvall biopsy operates by to the outer tube stopping against the needle head in the closing motion. Additionally, the final millimeter in the closing motion is a soft close action in order to protect the needle head from too strong forces. To enable the soft closing action, the Forsvall biopsy gun has a design similar to the predicate device.

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

The Forsvall biopsy needle is intended to collect histological biopsy samples from soft tissue intended for clinical examination. The Forsvall biopsy needle is part of the Forsvall biopsy needle system for prostate biopsy and shall be used together with the Forsvall biopsy gun.
The Forsvall biopsy gun is intended to be used by medical professionals, together with the Forsvall biopsy needle, on male patients to obtain soft tissue samples. The Forsvall biopsy gun is part of the Forsvall biopsy needle system for prostate biopsy.

The Forsvall biopsy needle system for prostate biopsy is indicated whenever there is a need to obtain prostate biopsy samples.

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

The Forsvall biopsy needle system for prostate biopsy is indicated for use for prostate biopsy only, whereas the predicate device (Möller) has multiple use indications where prostate biopsy is one (see Möller models: FNB, MBY, ABG, SBG + Model Möller Medical Blue RBG).

These differences are concluded to not constitute a new intended use since both predicate device models (as presented above) and the Forsvall biopsy needle system for prostate biopsy are intended to be used by the same user group, on the same patient group and for the same medical reasons.

Technological Comparison 21 CFR 807.92(a)(6)

The Forsvall biopsy system consists of the disposable biopsy needle and the reusable biopsy gun. The needle consist of a single use 16/18 gauge 10/15/20/25 cm needle in medical grade stainless steel with a side notch 20 mm pocket for biopsy sampling just as the preducate device. The biopsy gun is spring loaded and has the same principle of action using the same spring force, the same design and materials and moving the needle in the same principal way as the predicate device.

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

The main non-clinical testing that was done to determine substantial equivalence:

-User Testing: Users have fired the biopsy gun into a biopsy model to confirm that it performs as expected in a simulated clinical setting.
-Dimensional Verification: Confirmed that the needle dimensions are appropriate to achieve the proper sample length.
-Needle Specifications: Verified that the needle length and diameter are suitable.
-Sample Retrieval: Validated that a tissue sample can be effectively removed using the needle.
-Needle Gap Minimization: Confirmed that the gap between the needle components is minimized to limit patient exposure of in-vivo bacteria.
-Needle Tip Quality: Ensured that the needle tip is smooth and free from defects, which is crucial for patient safety and procedure efficacy.
-Shelf life and transport testing.

See bench_tests.pdf and user_tests.pdf for details.

N/A

All non-clinical tests related to performance as described above passed. Risk management was performed according to ISO 14971. Design properties and risks scenarios that differs from the predicate device have been assessed and concluded to be either state-of-the-art or related to a risk control measure where the benefit is deemed greater than the risk.

The device is therefore at least as good as the predicate device with respect to safety, effectiveness and performance