Fujifilm Corporation
% Chaitrali Kulkarni
Sr. Regulatory Affairs Specialist
Fujifilm Healthcare Americas Corporation
81 Hartwell Ave., Suite 100
Lexington, Massachusetts 02421

August 12, 2026

Re: K261170
Trade/Device Name: BA-004CC
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: Class II
Product Code: ITX
Dated: July 16, 2026
Received: July 16, 2026

Dear Chaitrali Kulkarni:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Digitally signed by Michael D. O'hara -S
Date: 2026.08.12 12:54:01 -04'00' For

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261170

Please provide the device trade name(s).

BA-004CC

Please provide your Indications for Use below.

This device provides doctors with a tool for performing needle/instrument guided procedures with the use of diagnostic ultrasound probes. It is disposable and provided to the user sterile.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) #: K261170

510(k) Summary

Prepared on: 2026-07-16

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Fujifilm Corporation
Applicant Address	798 Miyanodai, Kaisei-machi Ashigarakami-gun Kanagawa 258-8538 Japan
Applicant Contact Telephone	704-517-4886
Applicant Contact	Ms. Chaitrali Kulkarni
Applicant Contact Email	hcusregulatoryaffairs@fujifilm.com
Correspondent Name	Fujifilm Healthcare Americas Corporation
Correspondent Address	81 Hartwell ave suite 100 Lexington MA 02421 United States
Correspondent Contact Telephone	704-517-4886
Correspondent Contact	Ms. Chaitrali Kulkarni
Correspondent Contact Email	hcusregulatoryaffairs@fujifilm.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	BA-004CC
Common Name	Diagnostic ultrasonic transducer
Classification Name	Transducer, Ultrasonic, Diagnostic
Regulation Number	892.1570
Product Code(s)	ITX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K222052	VitroPRO	ITX

Device Description Summary

21 CFR 807.92(a)(4)

Intended use

- This device provides doctors with a tool for performing needle/instrument guided procedures with the use of diagnostic ultrasound probes. It is disposable and provided to the user sterile.

General description

- This device provides physicians with a tool for performing needle/instrument guided procedures with the use of diagnostic ultrasound endocavity transducers.
- Transrectal - Diagnostic ultrasound needle / instrument guided procedures such as tissue biopsy.
- Transvaginal - Diagnostic ultrasound needle / instrument guided procedures such as tissue biopsy.

Principle of operation and features
• The puncture direction is fixed by attaching it to the ultrasound diagnostic probe and forming a puncture path with the guide tube of the puncture adapter body.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

This device provides doctors with a tool for performing needle/instrument guided procedures with the use of diagnostic ultrasound probes. It is disposable and provided to the user sterile.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Although the expression is different, it is the same when performing ultrasound-guided transrectal tissue biopsies, transvaginal tissue biopsies.

Technological Comparison

21 CFR 807.92(a)(6)

The device has the same technological characteristics as the predicate device and it provides physicians with a tool for performing needle/instrument guided procedures with the use of diagnostic ultrasound endocavity transducers.
• Transrectal - Diagnostic ultrasound needle / instrument guided procedures such as tissue biopsy.
• Transvaginal - Diagnostic ultrasound needle / instrument guided procedures such as tissue biopsy.

The device has the same principles of operation as the predicate device and its puncture direction is fixed by attaching it to the ultrasound diagnostic probe and forming a puncture path with the guide tube of the puncture adapter body.

The device and the predicate device utilize the same types of ABS thermoplastic and stainless steel. Biocompatibility testing has been conducted for all new materials as recommended by regulatory standards, and no new safety or effectiveness concerns have been identified.

Although the sterilization methods employed for the device and the predicate device differ, both methods are established and recognized processes. Sterilization validation has been performed for the device, and no new issues regarding safety or effectiveness have been identified.

The shelf life differs between the device and the predicate device; however, stability testing has demonstrated that there are no new safety or effectiveness concerns within the specified period.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The performance of the proposed device was evaluated according to the engineering requirements listed in this section. In all cases, the devices met the pre-defined acceptance criteria for the tests.
- Verified that the device can be properly connected to the probe and probe cover for application.
- Confirmed that the holding force of the puncture adapter during attachment meets the required standards.
- Ensured that the PTC needle can be inserted smoothly without excessive force.
- Assessed whether the puncture accuracy of the puncture adapter complies with the required specifications.

Although there are minor differences between the proposed and predicate devices, these differences do not raise new or additional questions of safety or effectiveness of the proposed device. Thus, the proposed device is substantially equivalent to the predicate device and reference devices.

In all cases, the device met the pre-defined acceptance criteria for the tests. This demonstrates that the device has safety, effectiveness, and performance comparable to those of the predicate device.