



July 18, 2025

OnePass Medical Ltd.
% Danielle Besal
Principal Consultant
MRC Global
9085 East Mineral Circle
Centennial, Colorado 80112

Re: K251542
Trade/Device Name: InstaFAN
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: ODG, FCG
Dated: May 20, 2025
Received: May 20, 2025

Dear Danielle Besal:

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,

SIVAKAMI VENKATACHALAM -S

for

Shanil P. Haugen, Ph.D.

Assistant Director

DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices

OHT3: Office of Gastrorenal, ObGyn,

General Hospital and Urology Devices

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.

K251542

?

Please provide the device trade name(s).

?

InstaFAN

Please provide your Indications for Use below.

?

The InstaFAN device is intended for sampling targeted submucosal and extramural lesions within or adjacent to the gastrointestinal tract through the accessory channel of a curvilinear echo-endoscope. Use only with EUS endoscopes.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)
 Over-The-Counter Use (21 CFR 801 Subpart C)

?

510(k) #:

510(k) Summary

Prepared on: 2025-05-20

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	OnePass Medical Ltd.
Applicant Address	1st The Four Street Katzrin Industrial Park Katzrin 1290000 Israel
Applicant Contact Telephone	972.54.6670181
Applicant Contact	Jacob Ben Arie
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Correspondent Contact Telephone	9018278670
Correspondent Contact	Danielle Besal
Correspondent Contact Email	danielle.besal@askmrcglobal.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	InstaFAN
Common Name	Endoscope and accessories
Classification Name	Endoscopic Ultrasound System, Gastroenterology-Urology
Regulation Number	876.1500
Product Code(s)	ODG, FCG

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K160845	Acquire Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device	ODG

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

InstaFAN is an endoscopic ultrasound-guided fine needle aspiration/fine needle biopsy device that collects several samples from different locations in a single pass. The InstaFAN can be coupled to the biopsy channel of a Curvilinear Array (CLA) Echoendoscope and delivered to the gastrointestinal tract. The InstaFAN device is comprised of a central single 22-gauge needle and four peripheral 25-gauge needles. The device has a single handle design that contains two moving parts. The distal section of the handle controls the central needle, which can be activated first on its own or together with the proximal section of the handle to deploy all five needles simultaneously. The needles are used to acquire samples from lesions within and adjacent to the digestive system's major lumens that can be identified and targeted using the echoendoscope. Aspiration/biopsy samples are obtained by penetrating the lesion with the needle(s) while applying suction with the syringe.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The InstaFAN device is intended for sampling targeted submucosal and extramural lesions within or adjacent to the gastrointestinal tract through the accessory channel of a curvilinear echo-endoscope. Use only with EUS endoscopes.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The subject device includes a statement about use with EUS endoscopes; however, this is a clerical difference for enhanced clarity that does not impact the indications for use.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The subject InstaFAN device uses the same fundamental technology as the predicate device. The safety and effectiveness of the subject device has been verified and validated and performance was shown to be substantially equivalent. Thus, it can be concluded that the subject InstaFAN device does not raise different questions about safety and effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Performance testing was conducted on the InstaFAN device to verify the specifications of the device design. Testing included verification of the performance of the needles (tensile, elasticity, bend strength) as well as that of the overall device (EUS connection force, bend strength, force required to move needles, insertion force, and needle orientation). Results of the testing showed the device met its specifications. Animal studies were also conducted on the InstaFAN device and results met the safety and performance criteria to demonstrate substantial equivalence to the predicate.

Clinical testing was not required for the subject device; therefore, this section is not applicable.

The InstaFAN device uses the same fundamental technology as the predicate device. The differences between the InstaFAN device and its predicate device do not introduce a new intended use and do not raise different questions of safety and effectiveness. Verification and validation testing demonstrated that the device performs as intended. From the results of nonclinical testing, OnePass Medical concludes that the InstaFAN device is substantially equivalent to the predicate device.