December 29, 2022

Itamar Medical, Ltd.
% Jonathan Kahan
Partner
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, District of Columbia 20004-1109

Re: K211557
Trade/Device Name: EndoPATx
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: May 19, 2021
Received: May 19, 2021

Dear Jonathan Kahan:

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,

Robert T. Kazmierski -S

for

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular 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)*

K211557

Device Name

EndoPATx

Indications for Use *(Describe)*

The EndoPATx device is a non-invasive device intended for use as a diagnostic aid in the detection of coronary artery Endothelial Dysfunction (positive or negative) using a reactive hyperemia procedure.

The EndoPATx has been shown to be predictive of coronary artery Endothelial Dysfunction in the following patient population: patients with signs or symptoms of ischemic heart disease, who are indicated for coronary artery angiography, but who lack angiographic evidence of obstructive coronary artery disease. The device is intended to be used in a hospital or clinic environment by competent health professionals.

The EndoPATx device is not intended for use as a screening test in the general patient population. It is intended to supplement, not substitute, the physician's decision-making process. It should be used in conjunction with knowledge of the patient's history and other clinical findings.

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

Itamar Medical Ltd.'s EndoPATx

1. Submitter's Identification

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3. Date Prepared

November 30, 2022

4. Name of Device

Trade Name: EndoPATx
Common or Usual Name: Computer, Diagnostic, Programmable
Classification: 21 CFR 870.1425
Classification Name: Programmable Diagnostic Computer
Regulatory Class: II
Product Code: DQK
Product Code Name: Computer, Diagnostic, Programmable

5. Predicate Device Information

Predicate: EndoPAT2000 ("EP2000") (Itamar Medical Ltd.), K032519; product code DQK (Programmable Diagnostic Computer)

6. Device Description

The EndoPATx is a non-invasive system for assessing vascular endothelial function. It is based on the use of Peripheral Arterial Tone (PAT) technology which measures post-ischemic vascular response following arm blood flow occlusion.

It is intended for use as a diagnostic aid in the detection of presence coronary artery Endothelial Dysfunction using a reactive hyperemia procedure in the following patient population: patients with signs or symptoms of ischemic heart disease, who are indicated for coronary artery angiography, but who lack angiographic evidence of obstructive coronary artery disease. The device is intended to be used in a hospital or clinic environment by competent health professionals.

It is not intended for use as a screening test in the general patient population. It is intended to supplement, not substitute, the physician's decision-making process. It should be used in conjunction with knowledge of the patient's history and other clinical findings.

7. Indications for Use

The EndoPATx device is a non-invasive device intended for use as a diagnostic aid in the detection of coronary artery Endothelial Dysfunction (positive or negative) using a reactive hyperemia procedure.

The EndoPATx has been shown to be predictive of coronary artery Endothelial Dysfunction in the following patient population: patients with signs or symptoms of ischemic heart disease, who are indicated for coronary artery angiography, but who lack angiographic evidence of obstructive coronary artery disease. The device is intended to be used in a hospital or clinic environment by competent health professionals.

The EndoPATx device is not intended for use as a screening test in the general patient population. It is intended to supplement, not substitute, the physician's decision-making process. It should be used in conjunction with knowledge of the patient's history and other clinical findings.

8. Summary of Technological Characteristics and Comparison

The clinical set-up, mode of operation and the output measurement of the subject device are identical to the proposed predicate (K032519). Both the predicate and the subject devices are non-invasive devices intended for use as a diagnostic aid in the detection of coronary artery Endothelial Dysfunction using a reactive hyperemia procedure.

The principles of operation of the EndoPATx are identical to those of the predicate, also developed by Itamar Medical. Both devices use Peripheral Arterial Tone (PAT) Technology to measure post-ischemic vascular response following the release of blood flow occlusion of one arm while the other arm serves as control. In both devices the PAT probes are placed on the patient's index fingers on both hands, one on the occluding side and one on the control, sensing the finger pulsatile volume changes and the magnitude and dynamics of the PAT signal changes. Both the predicate device and the subject device use the same analysis algorithms and the same scores are calculated in both devices.

The technological characteristics of the subject device are similar to the predicate device. The hardware and the software algorithms of the subject device are similar to the predicate device and provide equivalent functionality and performance features.

The subject device is a modern replica of the predicate device, with several modifications replacing some of the old and obsolete hardware components and to introduce an updated user interface addressing enhanced usability (see comparison **Table VII-1**).

Table VII-1: Comparison Table

Parameter	Subject Device	EndoPAT2000 K032519	Comparison
Intended Use	The EndoPATx device is a non-invasive device intended for use as a diagnostic aid in the detection of coronary artery Endothelial Dysfunction (positive or negative) using a reactive hyperemia procedure. The EndoPATx has been shown to be predictive of coronary artery Endothelial Dysfunction in the following patient population: patients with signs or symptoms of ischemic heart disease, who are indicated for coronary artery angiography, but who lack angiographic evidence of obstructive coronary artery disease. The device is intended to be used in a hospital or clinic environment by competent health professionals. The EndoPATx device is not intended for use as a screening test in the general patient population. It is intended to supplement, not substitute, the physician's decision-making process. It should be used in conjunction with knowledge of the patient's history and other clinical findings.	The EndoPAT™2000 device is a non-invasive device intended for use as a diagnostic aid in the detection of coronary artery Endothelial Dysfunction (positive or negative) using a reactive hyperemia procedure. The EndoPAT™2000 Device has been shown to be predictive of coronary artery Endothelial Dysfunction in the following patient population: patients with signs or symptoms of ischemic heart disease, who are indicated for coronary artery angiography, but who lack angiographic evidence of obstructive coronary artery disease. The device is intended to be used in a hospital or clinic environment by competent health professionals. The EndoPAT™2000 device is not intended for use as a screening test in the general patient population. It is intended to supplement, not substitute, the physician's decision-making process. It should be used in conjunction with knowledge of the patient's history and other clinical findings.	Identical
Class	II	II	Identical
Regulation	21 CFR 870.1425	21 CFR 870.1425	Identical
Code	DQK	DQK	Identical
510k number	N/A	K032519	N/A
Device Components	• Two EndoPAT Probes • EndoPAT connector cables (Pneumo-electric tubing)	• Two EndoPAT Probes • EndoPAT connector cables (Pneumo-electric tubing)	The EndoPAtx has new Data Acquisition System (DAS) with newly developed

Parameter	Subject Device	EndoPAT2000 K032519	Comparison
	• EndoPATx Data Acquisition System (DAS) • Standard, MS-Windows based personal computer (PC) • EndoPAT accessories: -Finger Anchor -Arm Support -Cuff Set	• EndoPAT2000 Data Acquisition System (DAS) • Standard, MS-Windows based personal computer (PC) • EndoPAT accessories: -Finger Anchor -Arm Support -Cuff Set	electronics by use of current / state of the art components. The improvement does not raise different questions of safety or effectiveness. The EndoPATx accessories are identical to the EndoPAT2000 accessories.
Environment	Hospital or clinic	Hospital or clinic	Identical
Prescription	Prescription Use Only	Prescription Use Only	Identical
Clinical Procedure	Baseline Recording, Occlusion, Release and Post Occlusion Recording.	Baseline Recording, Occlusion, Release and Post Occlusion Recording.	Identical
System TLD (Top Level Domain)	PAT Probes, connected to Data Acquisition System, connected and controlled by PC, patient data storage and patient database managed by the PC.	PAT Probes, connected to Data Acquisition System, connected and controlled by PC, patient data storage and patient database managed by the PC.	Identical
Scores	• Reactive Hyperemia Index (RHI and LnRHI) • Heart rate (HR)	• Reactive Hyperemia Index (RHI) • Heart rate (HR)	Usability improvement. In addition to the RHI that is presented in a linear scale, an optional presentation in a logarithmic scale (LnRHI) was added. The calculation remains the same. Heart rate: Identical
Analysis algorithms	Identical		
Main Electrical Design (PCB)	New design that supports the use of the new digital output pressure sensors and USB communication with host computer.		Technical improvement. Use of current / state of the art components.
Power Supply	12VDC 2.50A (30W) internal medical-grade power supply	12VDC 2.00A (24W) external medical-grade power supply	Usability improvement. The internal Power Supply Unit (PSU) is an integral unit of the system, therefore confusion with a

Parameter	Subject Device	EndoPAT2000 K032519	Comparison
			different PSU is avoided and so is the risk of connecting a non-medical grade PSU. Increasing the power to 30W increases the worst-case power consumption margin.
LED Indications	3 – ON, Error, Communication	2 – ON and Communication	Usability improvement. Additional error indication on the device. Addition of the Error indication does not raise different questions of safety and effectiveness.
Connectivity	USB	RS232 + USB adapter	Usability improvement. Avoid the need for the USB adapter. This improvement does not raise different questions of safety and effectiveness.
Finger Probe	Pneumatic PAT Probe for EndoPATx. Internal coating of the probe made from Neoprene; a standard material used for surgical gloves.	Pneumatic PAT Probe for EndoPAT2000. Internal coating of the probe made from Latex.	Biocompatibility improvement. Internal coating changed to a material which is less allergenic than latex. The change does not raise different questions of safety and effectiveness.
Cables	Electronic – Air Lumen Cable	Electronic – Air Lumen Cable	Identical
Data Archiving	In database and files	In files	Technical Improvement. Direct access to data without the need to parse data in files.

Parameter	Subject Device	EndoPAT2000 K032519	Comparison
			Data is secured and there is automatic backup. Access control is seamlessly implemented by user's role. This improvement does not raise different questions of safety and efficacy.
SW User Interface	New Graphical User Interface (GUI): • Same functionality • User interface was updated	GUI	Usability improvement. Use of current / state of the art user interface. This improvement does not raise different questions of safety and efficacy.

9. Summary of Performance Data

A series of safety and performance tests were performed to demonstrate that the EndoPATx is substantially equivalent to the predicate system. These tests include:

• Data Acquisition System (hardware (HW) and firmware (FW)) functional tests for the EndoPATx.
• Electrical Safety testing per AAM/ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012.
• Electromagnetic compatibility testing per IEC 60601-1-2:2014, 4th Edition.
• Mechanical tests: transportation tests.
• Software verification and validation testing was performed to demonstrate that the software in the subject device meets design specifications.
• Information Security Tests (part of software (SW) test) to verify access control with username and password.
• Equivalency testing to verify that the performance of EndoPATx is substantially equivalent to its predicate device, EndoPAT2000. Technical equivalency tests are divided as follows: 1) PAT signal acquisition input/output equivalency tests; 2) Scoring equivalency tests.

The testing above demonstrated that the EndoPATx is substantially equivalent to its predicate and the proposed modifications do not raise any different questions of safety or effectiveness.

10. Conclusions

Based on the comparison of intended use, indications for use, technological characteristics and performance testing, Itamar Medical Ltd. believes that the EndoPATx is substantially equivalent to its predicate.