June 28, 2018

Deltex Medical Limited
Mark Baylis
Quality & Regulatory Affairs Director
Terminus Road
Chichester, PO19 8TX Gb

Re: K172457
Trade/Device Name: Deltex Medical CardioQ-EDM+, Deltex Medical CardioQ-EDM
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II
Product Code: DPW
Dated: May 24, 2018
Received: May 29, 2018

Dear Mark Baylis:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172457

Device Name
Deltex Medical CardioQ-EDM and Deltex Medical CardioQ-EDM+

Indications for Use *(Describe)*

The CardioQ-EDM series fluid management and cardiac output monitoring systems are designed to provide clinicians with real-time information about patients left ventricular blood flow and key hemodynamic parameters. The CardioQ-EDM series beat to beat data on cardiovascular status can be used by the managing clinician to evaluate and optimize hemodynamic performance in anesthetized, sedated or conscious patients in the operating room, intensive care unit, emergency room or ward.

The CardioQ-EDM series monitors when used in Flow Monitoring Mode (esophageal Doppler) or Pressure Monitoring Mode (EDM+ only) are intended for use with adult and pediatric patients. When the CardioQ-EDM series monitors are used for High-Definition Impedance CardioGraphy with a PhysioFlow Q-Link module the intended use is for adult patients only.

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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1.1.10 510(k) Summary

510(k) Summary

(as required by 21 CFR 807.92 (c))

Owner's Name:

Deltex Medical
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United Kingdom
Tel: 011 44 1243 523174
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Classification:

Proprietary Name:	Deltex Medical CardioQ-EDM Deltex Medical CardioQ-EDM+
Common/Usual Name:	Esophageal Doppler Monitor
Classification Name:	Cardiovascular Blood Flowmeter
Product Code:	DPW
Regulation Number:	21 CFR 870.2100

Predicate Devices used to Demonstrate Substantial Equivalence:

Primary Predicate - K132139 (Deltex Medical CardioQ EDM+ Esophageal Doppler Monitor, procode DPW)
Secondary Predicate - K140102 (Manatec Biomedical PhysioFlow Q-Link Module, procode DSB)

Description:

The CardioQ-EDM series are medical instruments designed to monitor cardiac function and fluid status. The CardioQ-EDM & EDM+ achieve this by combining Doppler measurements of the blood flow (4MHz continuous wave ultrasound) to monitor and quantify the blood flow in the descending thoracic aorta. In addition to this the CardioQ-EDM+ previously introduced as an upgrade to the EDM under (K132139) allows additional Pulse Pressure Waveform Analysis (PPWA) through arterial blood pressure based parameters slaved from a high-end monitor.

The CardioQ-EDM (K111542) & Cardio EDM+ (K132139) have now been introduced with the addition of a USB Hub accessory and software modifications that allow the CardioQ-EDM series monitors to display hemodynamic parameters from the coupled together hemodynamic impedance cardiography device.

The addition of USB Hub accessory and software modifications allow the CardioQ-EDM series monitors to become a non-invasive cardiac output measurement system which displays hemodynamic parameters, allowing analysis of a trans-thoracic impedance cardiography signal & cardiac output monitoring. The only addition to the CardioQ-EDM & CardioQ-EDM+ is the enabling of HD-ICG functionality through the USB Hub accessory introduction and software modifications to display the hemodynamic parameters from the coupled hemodynamic impedance cardiography device. The coupled device has already received Traditional 510(k) clearance under (K060387) dated 4th October 2010 and Special 510(k) clearance for module variants and updates under (K103283 Enduro Model) & (K140102 Q-Link Model) dated 3rd December 2010 & 12th February 2014 under class II classification per 21 CFR 870.2770.

This Traditional 510(k) is submitted for a change to the software of the Deltex Medical CardioQ-EDM (K134139) & EDM+ (K111542) series monitors.

Only the introduction of a USB Hub, software and related labelling has been updated to introduce additional functionality to allow the display of hemodynamic parameters from the coupled hemodynamic impedance cardiography device. This extends the functional scope of the CardioQ-EDM series to also be utilized as a non-invasive cardiac output monitors displaying hemodynamic parameters, allowing analysis of a trans-thoracic impedance cardiography signal and cardiac output monitoring.

Intended Use:
The CardioQ-EDM series fluid management and cardiac output monitoring systems are designed to provide clinicians with real-time information about patients left ventricular blood flow and key hemodynamic parameters. The CardioQ-EDM series beat to beat data on cardiovascular status can be used by the managing clinician to evaluate and optimize hemodynamic performance in anesthetized, sedated or conscious patients in the operating room, intensive care unit, emergency room or ward.

The CardioQ-EDM series monitors when used in Flow Monitoring Mode (esophageal Doppler) or Pressure Monitoring Mode (EDM+ only) are intended for use with adult and pediatric patients. When the CardioQ-EDM series monitors are used for High-Definition Impedance CardioGraphy with a PhysioFlow Q-Link module the intended use is for adult patients only.

Comparison of technological features:

The Deltex Medical CardioQ-EDM series are substantially equivalent in design, use and materials to the: Deltex Medical CardioQ-EDM+, 510(k) number: K132139 and Deltex Medical CardioQ-EDM 510(k) number: K111542, only the software and related labeling has been updated. The primary change is to present additional functionality through the introduction of a USB Hub accessory and software modifications. The HD-ICG module is the secondary predicate K140102 with no technical changes.

This will allow the CardioQ-EDM series to display hemodynamic parameters from the coupled hemodynamic impedance cardiography device. The coupled device has already received Traditional 510(k) clearance under (K060387) dated 4th October 2010 and Special 510(k) clearance for module variants and updates under (K103283 Enduro Model) & (K140102 Q-Link Model) dated 3rd December 2010 & 12th February 2014.

The device and subsequently attached devices to it shall be responsible for all impedance cardiography and trans-thoracic analysis data. The CardioQ-EDM series monitors will only be coupled with the most current variant (K140102) of the impedance cardiography device and shall only be responsible in displaying the results of these calculations allowing cardiac output monitoring.

From the coupled device and subsequently attached devices, the following hemodynamic parameters are calculated which will be available for display from the CardioQ-EDM series monitors:

- HR: Heart Rate,
- SV: Stroke Volume,
- SVi: Stroke Volume Index,
- CO: Cardiac Output,
- CI: Cardiac Index,
- CTI: Contractility Index,
- VET: Ventricular Ejection Time,
- EDFR: Early Diastolic Filling Ratio,
- TFi: Thoracic Fluid Index,

The CardioQ-EDM series monitors will idle Doppler measurements of blood flow (4MHz continuous wave ultrasound) with Pulse Pressure Waveform Analysis (PPWA) when HD-ICG functionality has been enabled to subject the CardioQ-EDM series monitors to only display hemodynamic parameters subject to impedance cardiography.

Summary of Clinical and Non-Clinical Data:

Electrical Safety and Electromagnetic Compatibility:

Evaluation of both Electrical Safety and Electrical Compatibility has been conducted following IEC 60601 series of standards, which are FDA recognized voluntary consensus standards.

Acoustic Output Testing:

No Acoustic Output Testing has been conducted, because the CardioQ-EDM series monitors are only displaying data rather than performing any primary calculations. All calculations are conducted by the hemodynamic impedance cardiography device coupled to the CardioQ-EDM series monitors.

Bench Testing:

Comparative bench testing of the CardioQ-EDM series monitors using previously cleared under 510(k) (K140102) dated 12th February 2014, (PhysioFlow Q-Link) coupled device is included. The results of this testing support the software modifications and introduced USB Hub accessory have enabled additional HD-ICG functionality to be introduced to the existing CardioQ-EDM series monitors.

Code examination is also included to demonstrate that the software correctly displays the information received from the coupled hemodynamic impedance cardiography device without any manipulation of the coupled device.

Animal Testing:

No animal testing was conducted in support of this 510(k).

Clinical Testing:

No clinical testing was conducted in support of this 510(k).

Letter-to-File Changes

It should be noted that the following changes have been made under the Letter-to-File system:

- Addition of Cardiac Power (CPO) and Cardiac Power Index (CPI) in Nov 2013 - The pumping capability of the heart can be defined as the Cardiac Power Output (CPO(max)) achieved by the heart during maximal stimulation. The formulae are as follows:

  Cardiac Power (units expressed in Watts)

  $$\mathrm{CPO} = \frac{(\mathrm{MAP} \times \mathrm{CO})}{451}$$

  Where MAP is mean arterial pressure and CO is cardiac output.

Cardiac Power Index

$$\mathrm{CPI} = \frac{\mathrm{CPO}}{\mathrm{BSA}}$$

Where CPO is cardiac power and BSA is the body surface area.

The following papers have validated the use of CPO and CPI:

- Rupert Fincke, Judith S. Hochman, April M. Lowe, Venu Menon, James N. Slater, John G. Webb, Thierry H. LeJemtel and Gad Cotter: Cardiac Power Is the Strongest Hemodynamic Correlate of Mortality in Cardiogenic Shock: A Report From the SHOCK Trial Registry. J Am Coll Cardiol 2004;44:340–8.

- SG Hall, J Garcia, DF Larson and R Smith: Cardiac power index: staging heart failure for mechanical circulatory support: Perfusion 27(6) 456 –461, 2012.

- Karl Werdan, Martin Ruß, Michael Buerke, Georg Delle-Karth, Alexander Geppert and Friedrich A Schöndube: Cardiogenic Shock Due to Myocardial Infarction: Diagnosis, Monitoring and Treatment A German-Austrian S3 Guideline: Dtsch Arztebl Int. 2012 May; 109(19): 343–351.

- Addition of Elastance (Ea) and Dynamic Arterial Elastance (Eadyn) in Feb 2017 – The effective arterial Elastance (Ea), provides a valid measure of arterial load in humans. Dynamic Arterial Elastance Eadyn is the functional assessment of arterial load and is defined as the ratio between pulse pressure variation (PPV) and stroke volume variation (SVV). The formulae are as follows:

Elastance

$$\mathrm{Ea} = \frac{(0.9 \times \mathrm{P}_{SYS})}{\mathrm{SV}}$$

Where Psys is systolic pressure and SV is stroke volume.

Dynamic Arterial Elastance

$$\mathrm{Ea}_{dyn} = \frac{\mathrm{PPV}}{\mathrm{SVV}}$$

Where PPV is pulse pressure variation and SVV is stroke volume variation.

The following papers have validated the use of the formulae used for Ea and Eadyn:

- RP Kelly, CT Ting, TM Yang, CP Liu, WL Maughan, MS Chang and DA Kass; Effective arterial elastance as index of arterial vascular load in humans Circulation 1992;86;513-521.

- Fabio Guarracino, Rubia Baldassarri, and Michael R Pinsky; Ventriculo-arterial decoupling in acutely altered hemodynamic states: Critical Care 2013, 17:213.

- M. I. Monge Garcia, M. G. Romero, A. Gil Cano, H. D. Aya, A.Rhodes, R. M. Grounds and M. Cecconi; Dynamic arterial elastance as a predictor of arterial pressure response to fluid administration: a validation study; Critical Care. 2014; 18(6):626.

Conclusions:

Based on the testing completed and the comparisons with predicate device, the CardioQ-EDM series monitors do not raise any new questions on safety and effectiveness and the results support a determination of substantial equivalence.