



Huntleigh Healthcare Ltd.  
% Mr. Steve Monks  
QRE Compliance Director  
35 Portmanmoor Road  
Cardiff, CF24 5HN  
UNITED KINGDOM

February 19, 2021

Re: K201425

Trade/Device Name: Disposable Intraoperative Probe (DIOP8)  
Regulation Number: 21 CFR 892.1570  
Regulation Name: Diagnostic ultrasonic transducer  
Regulatory Class: Class II  
Product Code: ITX  
Dated: December 14, 2020  
Received: December 28, 2020

Dear Mr. Monks:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.  
Director  
Division of Radiological Health  
OHT7: Office of In Vitro Diagnostics  
and Radiological Health  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K201425

Device Name

Disposable Intraoperative Probe (DIOP8)

Indications for Use (Describe)

The DIOP8 surgical Doppler is indicated for use by qualified healthcare practitioners in a sterile condition in the operating theatre for the assessment of vascular blood flow by direct application to the vessel wall.

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**  
**K201425**  
**Disposable Intraoperative Probe**

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Prepared: May 2020

Contact: Steve Monks – QRE Compliance Director

## 5.1 Device Information

Device Name:	Disposable Intraoperative Probe (DIOP8)		
Regulation Name:	Diagnostic Ultrasonic Transducer		
Classification Name:	Transducer, Ultrasonic, Diagnostic		
Classification	Class	Product Code	Classification Regulation
	II	ITX	892.1570

## 5.2 Identification of Legally Marketed Devices to which Equivalence is claimed

Predicate Device:	IOP8 Intraoperative Probe (K032315) manufactured by Huntleigh Healthcare Ltd., Diagnostic Products Division.		
Regulation Name:	Diagnostic Ultrasonic Transducer		
Classification Name:	Transducer, Ultrasonic, Diagnostic		
Classification:	Class	Product Code	Classification Regulation
	II	ITX	892.1570

## 5.3 Indications for Use

Indications for Use:	The DIOP8 surgical Doppler is indicated for use by qualified healthcare practitioners in a sterile condition in the operating theatre for the assessment of vascular blood flow by direct application to the vessel wall.
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## 5.4 Description

Description :	<p>The DIOP8 is a sterile, single use, high sensitivity probe that assists in the performance of safe surgery. It is a lightweight, 8MHz ultrasound, handheld pencil probe' that has a small diameter tip that enables the detection of blood flow in vessels.</p> <p>The DIOP8 ultrasound probe operates in pulsed-wave mode. It has one circular piezo-electric crystal that is mounted behind the front faceplate and the crystal is used for both transmit and receive functions. The DIOP8 is manufactured at a frequency of 8MHz. The output ultrasonic parameters are fixed during the manufacturing process and cannot be adjusted by the user.</p> <p>A connector system at the end of the cable allows the DIOP8</p>
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to be removed from the hand held Doppler. An interconnection adapter houses the bi-directional electronics, which are specific for the device application, and is required as an interface between the main unit and DIOP8. The connector is similar to a conventional connector, but has no external conductive contacts, and is totally sealed, thus preventing the ingress of fluid and contaminants. Within the connector is a small coil that transfers electrical energy to and from a similar, but larger coil in the corresponding socket at the end of the PA8/PA8XS adapter. Transmitted and received electrical signals are passed through this connector, but there is no direct electrical connection between the probe and the PA8/PA8XS adapter. The connector provides electrical isolation between the probe and the PA8/PA8XS adapter, which optimises system electrical safety by limiting patient leakage currents to very low levels. During use, the adapter is securely held in the probe holder that is an integral part of the Doppler main unit. When connected this way, the hand held Doppler unit operates as if a normal VP8 probe is connected.

The DIOP8 is compatible for use with the following Doppler units, all manufactured by Huntleigh Healthcare and have FDA clearance:

- SD2 (Letter to File K930200)
- D900 (Letter to File K930200)
- DMX / DMXR (K183574)

#### Models

- DISP10XS
- DISP10
- DIPP10
- DISP10XS-DMX
- DISP10-D900
- DISP10-SD2
- ISP
- ISPXS

The DISP10XS model contains 10xDIOP8 probes, a PA8XS adapter and a Pole Clamp (ACC47).

The DISP10 model contains 10xDIOP8 probes, a PA8 adapter and a Pole Clamp (ACC47).

The DIPP10 model contains 10xDIOP8 probes.

The DISP10XS-DMX contains the same as the DISP10XS model, with a DMXR Handheld Doppler added (cleared under K183574).

The DISP10-D900 contains the same as the DISP10 model, with a D900 Handheld Doppler added (cleared under

K930200).

The DISP10-SD2 contains the same as the DISP10 model, with a SD2 Handheld Doppler added (cleared under K930200).

The ISP is an Intraoperative Probe Starter Pack and includes a PA8 adapter and Pole Clamp (ACC47).

The ISPXS is an Intraoperative Probe Starter Pack and includes a PA8XS adapter and Pole Clamp (ACC47).

## 5.5 Comparison of Technological Characteristics with Predicate Device

Comparison of Technological Characteristics with Predicate Device:

Doppler ultrasound is the technological principle for both the subject and predicate device. It is based on a combination of a hand held Doppler unit, an intraoperative probe and a PA8/PA8XS adapter.

The subject and the predicate are based on the same technological elements:

Technological Element	IOP8	DIOP8
Type of energy used	Ultrasound	Ultrasound
Principle used to detect blood flow	Doppler	Doppler
Number of piezo-electric crystals present	1	1
Piezo-electric crystal diameter	3 mm	3 mm
Operating mode	Pulsed	Pulsed
Pulse repetition frequency	62.5 kHz	62.5 kHz
Transmit burst duration	8 µs	8 µs
Receive window duration	7 µs	7 µs

The following technological differences exist between the subject device and predicate device:

Technological Element	IOP8	DIOP8
Piezo-electric crystal material	PZ27 ceramic	NCE51 ceramic
Probe length	130 mm	126 mm

Probe diameter	5 mm	5 mm
Probe tube material	Stainless steel	ABS thermoplastic
Probe faceplate material	Fortron PPS	ABS thermoplastic

Review of differences:

- Piezo-electric crystal material – PZ27 is manufactured by Ferroperm, whereas NCE51 is manufactured by Noliac. The specification references are different, but the material properties are similar. The materials are equivalent in the intraoperative probe application.
- Probe length – The DIOP8 is slightly shorter than the IOP8 (by 4mm). Usability evaluations have verified that there is no impact on probe usability, therefore this difference is insignificant.
- Probe tube material – The IOP8 tube material is stainless steel, whereas the DIOP8 tube material is ABS thermoplastic. The IOP8 can be re-sterilized using high temperature steam (autoclave method), hence stainless steel was chosen for compatibility. The DIOP8 however, is sterilised once only at the end of the manufacturing process using ethylene oxide (ETO), at a much lower temperature. This allowed the selection of ABS thermoplastic as the material for this component. Usability evaluations have verified that the probe is sufficiently rigid to perform its clinical function. Biocompatibility data is also provided for this material.
- Probe faceplate material – The faceplate is the area of the probe at the front, which is applied to the blood vessel during surgery. The IOP8 faceplate is made from Fortron PPS, which was selected due to the requirements for the probe to be compatible with high temperature steam (autoclave) sterilisation, as PPS is able to withstand high temperatures. The DIOP8 however, is sterilised once only at the end of the manufacturing process using ethylene oxide (ETO), at a much lower temperature. This allowed the selection of ABS thermoplastic as the material for this component. Biocompatibility data is also provided for this material.

## 5.6 Substantial Equivalence

Substantial Equivalence:

The DIOP8 is substantially equivalent to cleared device IOP8 Intraoperative Probe. The DIOP8 has equivalent performance to the IOP8 Intraoperative Probe.



## 5.7 Performance Data

Testing to demonstration substantial equivalence included:

Testing Conducted	Discussion
Biocompatibility Testing -Cytotoxicity -Sensitization -Irritation -Acute Systemic Toxicity	The biocompatibility evaluation of the device was conducted in accordance with <i>ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process</i> . The subject device is considered an external communicating device, contacting patient tissue (outer surface of blood vessels) for a limited duration of ≤24 hours.
Mechanical Performance Testing	Testing provides verification of mechanical performance including general, physical, environment, product labelling, instructions for use, packaging, durability and life testing.
Functional Performance Testing	Testing included acoustic output measurements completed by a third party laboratory, NPL, in accordance with both IEC 60601-2-37:2007+A1:2015 and Track 1 of the FDA guidance. Testing confirmed the subject device did not exceed the recommended acoustic output exposure levels.  Additionally, clinical measurement accuracy testing was completed in-house via a string phantom method.
Electrical Safety Testing	Electrical safety testing was conducted on the product by a third party laboratory, UL. Testing confirms device complies with IEC 60601-1:2005 + A1:2012
EMC Testing	EMC testing was conducted on the product by a third party laboratory, Kiwa Compliance Laboratories. Testing confirms

	device complies with IEC 60601-1-2:2014.
Environmental Performance Testing	Testing provides verification of the operating temperature, humidity and pressure and non-operating temperature, humidity, pressure, shock and vibration.
Software	The functions of the DIOP8 probe are supported by software, and the software is previously cleared and installed on the ultrasound unit that supports the probe. The software package is identical to the predicate and no new software code was created for the subject device.

## 5.8 Technologies Summary

### Technologies Summary:

The DIOP8 single use intraoperative Doppler ultrasound probe uses very similar technology to that of the predicate device; the IOP8 intraoperative Doppler probe. The main difference is that the DIOP8 is single-use, whereas the IOP8 is reusable.

As the DIOP8 is sterilised once only at the end of the manufacturing process using ethylene oxide (ETO), it is manufactured from materials compatible with this process. The IOP8 and DIOP8 operate at the same ultrasound frequency, in the same pulsed operating mode. In use, they provide same functionality; that is to evaluate blood flow within a vessel during surgery. They can be used with the same main Doppler units and PA8 adapters. Both the IOP8 and DIOP8 have the same intended use and indications for use. Where there are material differences, they mainly exist due to the different sterilization requirements, and biocompatibility data is available in this submission for these differences.

## 5.9 Conclusion

### Conclusion:

The data detailed within this submission demonstrates that the DIOP8 is safe, effective and performs as well as the predicate device identified in this summary, which is currently marketed for the same intended use. The device's mechanical and functional performance verification demonstrates that it should perform as intended in the specified user conditions.