A. Submitter information

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- Date of the summary: 27/07/2018

B. Device identification

- Trade name: TCD-X Transcranial Doppler Ultrasound System

- Common Name: Transcranial Doppler (TCD) Ultrasound system with robotized probe
  Transcranial Doppler Holter with robotized probe

- Federal Regulation Number: 21 CFR 892.1550 System, Imaging, Pulsed Doppler, Ultrasonic
  21 CFR 892.1570 Diagnostic Ultrasound Transducer

- Model Number(s): TCD-X system
  18263 (Monitoring Robotized probe 2MHz)
  22673 (Handheld probe 2MHz)

- Class: Class II medical device

- Product Code: IYN

- Subsequent Product Code: ITX

C. Identification of predicate device

- Predicate devices: EMS9UA (K122710) manufactured by Shenzhen Delicate Electronics Co., Ltd. (Codes IYN, ITX and OQQ)

D. Performance Standards

There are no required performance standards under the Federal Food, Drug and Cosmetic Act. Voluntary standards to which we will conform include: IEC 60601-1, IEC 60601-1-2, IEC 62304, IEC 60601-2-37 and ISO 10993.

E. Indication for use

The TCD-X is a transcranial Doppler device intended for recording non-invasively Doppler signals from intracranial vessels.

- For the display and measurement of cerebral artery blood flow velocities to determine the presence of hemodynamically significant deviations from normal values.
- For the detection of micro-embolic signals

TCD-X has the ability to be used as Holter mode on ambulatory patients.
The Robotic probe facilitates monitoring use by its ability to track good Doppler signal all along recording time.
The device is not intended to replace other means of evaluating vital patient physiological processes.

- Intended patient population
  The TCD-X is intended to be applied on adult persons

- Intended operator
  The TCD-X shall be used by or on the order of physician.
  The device should be used by trained physicians.

- Intended environment
  The TCD-X shall be used in hospital environment or in common examination room of a professional environment.

- Mode of operation
  2 MHz probe (PW)

- Contraindications
  The TCD-X shall not be used on non-intact skin.
  The TCD-X probe is not for use on the eyes, fetal application and fetal monitoring.

F. Description

The TCD-X system is a unilateral, non-invasive Transcranial Portable or body-worn Ultrasound Diagnosis Doppler. It is designed to non-invasively measure and display major transcranial vessels blood flow velocities that supply the brain. The system can also provide potential embolic events count.

It is composed by a recorder module, a robotized probe, a hand held probe and associated components (three available sizes for spectacle frames, small carrying bag, SD card, battery charger, USB cable).

TCD-X module needs to be connected to an external computer for its display, processing, archiving records and printing.

All probes are reusable, non invasive and non sterile. TCD-X can be fitted by one probe at a time.

It is fitted with 2MHz PW robotized monitoring probe, and 2MHz PW hand held probe.

The robotized probe has the ability to adjust its angle automatically to search the Doppler signal. When the Doppler signal becomes weaker during its recording, the orientation of the robotized probe can be adjusted automatically to retrieve a good quality signal.

TCD-X can be used in two modes: Holter mode or Desktop TCD mode.

The Holter mode is used on ambulatory patient. During the recording of the transcranial Doppler signal, the TCD-X is placed on the patient in a shoulder bag. The transcranial Doppler signal is recorded on a SD card. The recorded Doppler signal display and processing are made after examination on the computer.

The desktop TCD mode is a common conventional mode used for all TCD ultrasound Doppler. This mode allows the user to display the transcranial Doppler signal in real time. During this mode, the TCD-X remains connected to the PC via an isolated USB, the patient is immobile and the recording is done directly on the PC hard disk. The Doppler signal processing and printing is also possible after the end of real time recording.

G. Comparison of technological characteristics with the predicate device

Specification	TCD-X	EMS-9UA	Differences discussion
Manufacturer	ATYS	Shenzhen Delicate Electronics Co. Ltd.	NA
510(k) number	Proposed device	K122710	NA
Product codes Class	IYN, ITX Class II	IYN, ITX, OQQ Class II	Similar to predicate.
Intended use	The TCD-X is a transcranial Doppler device intended for recording non-invasively Doppler signals from intracranial vessels: - For the display and measurement of cerebral artery blood flow velocities to determine the presence of hemodynamically significant deviations from normal values. -For the detection of micro-embolic signals TCD-X has the ability to be used as Holter mode on ambulatory patients. The Robotic probe facilitates monitoring use by its ability to track good Doppler signal all along recording time. The device is not intended to replace other means of evaluating vital patient physiological processes. The TCD-X is intended to be applied on adult persons. The TCD-X shall be used by or on the order of physician. The device should be used by trained physicians.	The EMS-9UA Transcranial Doppler Ultrasound System is intended for use as a diagnostic ultrasound fluid flow analysis system: 1) For the measurement of cerebral artery blood velocities to determine the presence of hemodynamically significant deviations from normal values 2) To assess arterial cerebral blood flow for the occurrence of micro embolic signals. Vessels intended for observation include, but are not limited to the middle, anterior and posterior cerebral arteries, via the temporal windows, the vertebral mid basilar arteries via the foramen magnum and the ophthalmic artery and intracranial internal carotid artery via the eye. The Robo probe Headband facilitates monitoring use by its ability to track the Doppler signal. The EMS9UA Transcranial Doppler is intended for use during: a) Diagnostic exams b) Surgical interventions The device is not intended to replace other means of evaluating vital patient	Equivalent. The predicate device covers the TCD-X: Intended use, use environment, target users and patient population.

	The TCD-X shall be used in hospital environment or in common examination room of a professional environment. TCD-X is fitted either 2 MHz probe (PW) The TCD-X shall not be used on non-intact skin. The TCD-X probe is not for use on the eyes, foetal application and foetal monitoring.	physiological processes, is not intended to be used in fetal applications, and is not intended to be used inside the sterile field.	
Clinical applications	Intracranial	Intracranial Extracranial Peripheral	Equivalent. Predicate device covers clinical applications of TCD-X.
Energy delivered	Ultrasound energy	Ultrasound energy	Identical to predicate device.
Frequency modes / Transducers (MHz)	2MHz PW	2MHz PW 4MHz PW/CW 8MHz PW/CW	Equivalent. Predicate device covers frequency mode offered by TCD-X.
Mechanism of action	Doppler Ultrasound, with the following modes: Unilateral, mono-gate, Monitoring.	Doppler Ultrasound, with the following modes: Unilateral, Bilateral, Multigates, Monitoring, M-Mode.	Equivalent. Predicate device covers all mechanism of action of TCD-X.
TCD-X used as desktop TCD	1-Device used next to bedside of patients 2-Small box connected to external PC 3-Real time Display, recording and processing of Doppler signal on PC 4-Post processing of Doppler signal.	1-Device used next to bedside of patients 2-Small box connected to external PC 3-Real time Display, recording and processing of Doppler signal on PC 4-Post processing of Doppler signal.	Identical to predicate device.
TCD-X used as Holter	1-TCD-X body worn on ambulatory patients.	1-Device used next to bedside of patients 2-Small box connected to external PC	Equivalent Set up and post

	2-Small box connected to PC for setup only. 3- Doppler signal recorded on SD Card. 4-Doppler signal display and processing made after signal recording, downloading from SD card to PC.	during all examination. 3-Doppler signal recorded on PC. 4-Doppler signal display and processing during examination and after examination.	processing Doppler signal are similar to predicate device. Recording and method of use differences dot not impact adversely substantial equivalence to predicate device.
Transcranial monitoring probe.	2MHz PW reusable non sterile Robotic monitoring probe.	2MHz PW reusable non sterile Robotic monitoring probe.	Equivalent The mechanism of robotized probe is identical to EMS-9UA predicate device.
Transcranial handheld probe	2MHz PW reusable non sterile handheld probe	2MHz PW reusable non sterile handheld probe	Identical to predicate device.
Monitoring probe handling	-Spectacle frame with unilateral monitoring robotic probe	-Standard head frame with unilateral or bilateral monitoring robotic probes	Equivalent TCD-X method of fixation of robotic monitoring probe is equivalent to EMS-9UA predicate device. TCD-X method is effective and do not impact the substantial equivalence with predicate device for unilateral mode.
Power supply	Internally powered device using rechargeable Li-Ion battery	Mains	Equivalent This is user

	(8 hours autonomy)		convenience feature that does not impact the operation or safety of the patient.
Patient surface contact materials	Compatible	Compatible	Identical Patient surface contact probes materials are identical to all predicate devices from the same material/assembly manufacturer.
Performance	Sample volume adjustable	Sample Volume adjustable	Equivalent to predicate device.
	Depth adjustable	Depth adjustable	Equivalent to predicate device.
	Power: 0% to 100% where 100% represents Ispta.3 upper value that keeps the TIC (Cranial Thermal Index) in all configurations less than 1. Derated Ispta.3 is highly less than 720mW/cm2 within FDA guidance.	Power% 0 to 100% where 100% represents Ispta.3 upper-tolerance limit 720 mW/cm^2 within FDA guidance	Equivalent to predicate device.
Maximal acoustic output Ispta.3 (Mw/cm2)	Below maximal FDA guideline limits Comply with FDA limits: Ispta.3 ≤ 720 mW/cm2 MI ≤ 1.9 or the global maximum derated ISPPA ≤ 190 W/cm^2. TCD-X System global maximum MI and TIC (Cranial Thermal Index) are both designed to be <1.0 in all system configurations.	Below maximal FDA guideline limits Comply with FDA limits: Ispta.3 ≤ 720 mW/cm2 MI ≤ 1.9 or the global maximum derated ISPPA ≤ 190 W/cm^2.	Equivalent to predicate device.
Clinical measurements	-Peak velocity, -Mean velocity -End diastolic velocity,	-Peak velocity, -Mean velocity -End diastolic velocity,	Identical to predicate device

	-Pulsatility Index, -Resistance index, -Systolic to diastolic ratio, -Rise time, -Heart rate, -Emboli detection	-Pulsatility Index, -Resistance index, -Systolic to diastolic ratio, -Rise time, -Heart rate, -Emboli detection	
Velocity units	Cm/sec or kHz	Cm/sec or kHz	Identical to predicate device.
Display of the trends of indices	Available	Available	Identical to predicate device.
Audiogram display	Available	Available	Identical to predicate device.
Signal and audio playback	Available	Available	Identical to predicate device.
Configurable protocols	Available	Available	Identical to predicate device.
Export of patient reports	Multiple formats	Multiple formats	Identical to predicate device
Labeling and/or promotional materials	Leaflet User manual	Leaflet User manual	Equivalent
Standards Compliance	IEC 60601-1, 3.0 Ed. IEC 60601-1-2. 3.0 Ed. IEC 60601-2-37. 2.1 Ed ISO 10993 4.0 Ed IEC 62304 1.1 Ed	IEC 60601-1, 3.0 Ed. IEC 60601-1-2. 3.0 Ed. IEC 60601-2-37. 2.1 Ed ISO 10993 4.0 Ed	TCD-X complies with current recognized standards.
Box unit physical characteristics	Size: 15 x 9,2 x 2,8 cm Weight: 0.35 kg (without accessories)	Size: 34.3 cm × 21.9 cm × 6.3 cm Weight: 1.30 kg (without accessories)	Equivalent to predicate device

H. Substantial Equivalence Discussion

The TCD-X System is substantially equivalent to the EMS-9UA Transcranial Doppler Ultrasound System (K122710) based on indications for use and comparison of the functional capabilities. Both devices are intended to provide a diagnostic ultrasound fluid flow analysis. Features common to all systems include:

- Transcranial Doppler ultrasound systems used for fluid flow analysis
- Monitor the cerebral arteries via the temporal windows
- Utilize motorized probe and handheld probe for monitoring examinations
- Unilateral and Monogate measurements possible
- Use substantially equivalent operating modes
- Measure equivalent hemodynamic indices
- Have equivalent monitoring functions
- Display velocity spectrum
- Manufactured with materials that have been evaluated and found to be safe for the intended use of the device
- Have patient contact surfaces are manufactured from the same materials
- Manufactured to meet applicable physical, mechanical, and electrical safety

The TCD-X System is substantially equivalent to the EMS-9UA Transcranial Doppler Ultrasound System (K122710). This is based on the comparison of the indications for use and comparison of the functional capabilities. Both devices are intended to provide a diagnostic ultrasound fluid flow analysis.

The minor differences (discussed below) between the TCD-X System and the EMS-9UA Transcranial Doppler Ultrasound System (K122710) do not raise new questions of safety or effectiveness. These differences are discussed as follows:

I. TCD-X used as Holter

Contrary to the predicate device, the TCD-X can also be used as body-worn for ambulatory patients.

In this mode, the TCD-X is disconnected from the PC, put in its carrying bag, put on the patient and records the Doppler signal on the SD card.

The TCD-X is powered by a rechargeable Li-Ion battery to allow ambulatory examinations.

Before starting the recording TCD-X displays to the user the maximum duration recording. The user can select this maximum duration setting or can set lower duration of record.

This duration depends on the battery level of charge, available capacity on the SD card and Doppler parameters set.

The rechargeable battery in the TCD-X System is compliant with the IEC 62133 (First and Second Edition Rechargeable Lithium-Ion) and UL 1642 Standard for Lithium Batteries.

The robotized probe is used to track the Doppler signal during the monitoring. It is automated system that consists to change angles according to intensity level when monitoring. It is exactly the same system used with EMS-9UA and already cleared in (K122710).

J. Acoustic Output

Below maximal FDA guideline limits Comply with FDA limits: Ispta.3 ≤ 720 mW/cm2_MI ≤ 1.9 or the global maximum derated ISPPA ≤ 190 W/cm2.

TCD-X System global maximum MI and TIC (Cranial Thermal Index) are both designed to be <1.0 either in Desktop TCD or Holter mode.

EMS-9UA complies also with FDA limits Ispta.3 ≤ 720 mW/cm2. Cranial Thermal Index of EMS-9UA could exceed 1 but keeps always the user informed through the display.

K. Spectacle frame

The system that maintains the transcranial Doppler probe on the patient's head looks like a spectacle frame.

It can be used on awake or sedated patients.

For sedated patients (no movement, no complain about discomfort with wear), the spectacle type headframe allows the recording of a Doppler signal over several hours. It is equivalent to the headframe of the predicate device.

For awake patient, it is far more comfortable that the headframe of the predicate device. Indeed to prevent the probe from moving the headframe must be tight which is often painful after 20 min.

The spectacle type headframe has been designed to be comfortable.

The spectacle type headframe make possible longer recording or monitoring.

Clinical trials have been conducted with a prototype of TCD-X and points out that:

- Fixing the transducer in place with the spectacle frame resulted in recordings of better quality, and fewer manual adjustments were required compared with fixation with the standard headband.
- Patients tolerate recordings of 5 to 6 hours well
- There were no complaints of discomfort with the spectacle frame, whereas 3 of the 10 patients using the headband complained of a mild temporary headache due to pressure from the band.

No risk for the users or the patients was reported in this study.

The spectacle type headframe is manufactured by a manufacturer of spectacle frames. Biocompatible materials are used.

L. Summary of Non-Clinical Testing and Performance Standards

The TCD-X System is evaluated for acoustic output, biocompatibility, and accuracy, as well as thermal, electrical, electromagnetic, and mechanical safety. TCD-X meets the following standards and guidances:

- IEC 60601-1:2005+A1:2012 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2007 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 62304 Edition 1.1 2015-06 Medical device software - Software life cycle processes
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff, May 2005

- ISO 10993-1:2009/Cor.1:2010 Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
- IEC 60601-2-37: 2007(AMD1:2015) [Edition 2.1] - Medical Electrical Equipment -Part 2-37: Particular Requirements for The Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and Monitoring Equipment
- NEMA UD 2-2004 (R2009), Acoustic Output Measurement Standard For Diagnostic Ultrasound Equipment Revision 3
- UD 3-2004 (R2009) - Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment. Revision 2.
- Guidance for Industry and FDA Staff Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers: September 9, 2008
- Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process. Guidance for Industry and Food and Drug Administration Staff, Issued on June 16, 2016.

M. Clinical testing

Review of literature pertaining to the safety of the TCD-X has been conducted and appropriate specifications have been incorporated in the design of the TCD-X.
A clinical trial involving 97 patients were conducted to support the use of spectacle frame as robotic probe holder compared to the robotic headband of the predicate device and this was found to be safe and effective.
TCD-X has been subjected to extensive safety, performance testing and validation before release. All functional specifications, safety aspects following applicable standards, labeling requirements have been met and evaluated as safe and effective.

N. Conclusion

The increased mobility of TCD-X does not present any risk for the user or patient.
With the TCD-X, it is not only possible to measure the blood velocities in seated, rested or anaesthetized patients but also in patients involved in different routine activities.

As the patient can move during the recording of the Doppler signal, he or she withstand better the recording and accept better long-term recording which is relevant to record unpredictable or random phenomena.

The documentation provided demonstrates that:
• The TCD-X System and transducers are substantially equivalent to the predicate device.
• There are no new questions of safety and effectiveness concerning the TCD-X System and transducers.
• The TCD-X System is designed to be at least as safe and effective as the predicate device.
• The TCD-X System is designed to perform as well as the predicate device.

Accordingly, the TCD-X System is believed to be substantially equivalent to a predicate device of the same type which is lawfully distributed in interstate commerce in the United States and that differences do not raise any further questions of the safety or effectiveness.

Appendix G: Example Diagnostic Ultrasound Indications For Use Format

System: __TCD-X_____

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic			N				
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel							
Vessel	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Transducers that are marked by N for TCD-X system are already cleared by predicate device

Appendix G: Example Diagnostic Ultrasound Indications For Use Format

System: __TCD-X_____
Transducer: __2 MHz Robotic Probe: reference _____

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic			N				
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel							
Vessel	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Transducers that are marked by N for TCD-X system are already cleared by predicate device

Appendix G: Example Diagnostic Ultrasound Indications For Use Format

System: __TCD-X_____
Transducer: __2 MHz Handheld probe: reference _____

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic			N				
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel							
Vessel	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity ImagingTransducers that are marked by N for TCD-X system are already cleared by predicate device