510(K) SUMMARY

K183660

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92(c).

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2. Device Name: DP-10/DP-20/DP-30 Digital Ultrasonic Diagnostic Imaging System

Classification

Regulatory Class: II

Review Category: Tier II

21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (IYN)

21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (ITX)

3. Device Description:

The The DP-10/DP-20/DP-30 Digital Ultrasonic Diagnostic Imaging System is a

general purpose, portable/mobile (with mobile ultrasound trolley), software controlled, ultrasonic diagnostic system. Its function is to acquire and display ultrasound images in B-Mode, M-Mode, PW-Mode, Power Mode, THI or the combined mode (i.e. B/M-Mode, B/PW-mode, Power + B, Power + PW +B). This system is a Track 3 device that employs an array of probes that include linear array, convex array.

4. Indications for Use:

DP-10/DP-20/DP-30 Digital Ultrasonic Diagnostic Imaging System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ (breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac (adult, pediatric), peripheral vascular and urology exams.

5. Summary of Modifications

- New added Models:
  DP-10 Digital Ultrasonic Diagnostic Imaging System
- Main added Features
  iScanHelper.
- Indications For Use
  Added PW image Mode to all of the transducers of DP-20 and DP-30 Digital Ultrasonic Diagnostic Imaging System.
  Added Power image Mode to all of the transducers of DP-30 Digital Ultrasonic Diagnostic Imaging System.

6. Comparison with Predicate Devices:

DP-10/DP-20/DP-30 Digital Ultrasonic Diagnostic Imaging System is comparable with and substantially equivalent to these predicate devices:

Predicate Device	Manufacturer	Model	510(k) Control Number
1 Primary Predicate device	Mindray	DP-20/DP-30	K130833
2 Reference device	Mindray	Z5	K130695

3 Reference device	Mindray	M9	K171034

Compared to the predicate devices DP-20/DP-30 (K130833)

- DP-10/DP-20/DP-30 Digital Ultrasonic Diagnostic Imaging System employs the same technology as the predicate devices. All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, and calculations. The subject device also has the same intended uses and basic operating modes as the predicate devices.
- Subject device DP-10/DP-20/DP-30 has the same intended uses as the predicated device DP-20/DP-30 (K130833);
- The acoustic power levels of DP-10/DP-20/DP-30 are below the limits of FDA, which is the same as the predicated device DP-20/DP-30 (K130833).
- DP-10/DP-20/DP-30 is designed in compliance with the FDA recognized electrical and physical safety standards, which are the same as the predicated device DP-20/DP-30 (K130833).
- The new added features of DP-10/DP-20/DP-30 are the same as the predicated devices.

7. Non-clinical Tests:

DP-10/DP-20/DP-30 Digital Ultrasonic Diagnostic Imaging System has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical safety standards.

Non-clinical tests relied on in this premarket notification submission for a determination of substantial equivalence include testing showing compliance with the following standards:

- AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, c1:2009/(r)2012 and a2:2010/(r)2012 (consolidated text) medical electrical equipment - part 1: general requirements for basic safety and essential performance (iec 60601-1:2005, mod).
- IEC 60601-1-2 Edition 3: 2007-03, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests.

- IEC 60601-2-37 Edition 2.0 2007, Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.
- IEC 62304 Edition 1.1 2015-06, medical device software - software life cycle processes.
- IEC 62366-1 Edition 1.0 2015-02, Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]
- IEC 60601-1-6 Edition 3.1 2013-10, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
- ANSI AAMI ISO 10993-1:2009/(R)2013, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
- ISO 14971 Second edition 2007-03-01, medical devices - application of risk management to medical devices.
- NEMA UD 2-2004 (R2009), acoustic output measurement standard for diagnostic ultrasound equipment revision 3.

These non-clinical tests relied on in this premarket notification submission can support the determination of substantial equivalence of the subject device.

8. Clinical Studies

Not applicable. The subject of this submission, DP-10/DP-20/DP-30 Digital Ultrasonic Diagnostic Imaging System, does not require clinical studies to support substantial equivalence.

Conclusion:

Intended uses and other key features are consistent with traditional clinical practices, FDA guidelines and established methods of patient examination. The design, development and quality process of the manufacturer confirms with 21 CFR 820, ISO 9001 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards. Therefore, the DP-10/DP-20/DP-30 Digital Ultrasonic Diagnostic Imaging System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.