510(k) Summary

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Manufacturing Site:	Mdoloris Medical Systems SAS 270 rue Salvador Allende 59120 Loos France
Trade Name:	Mdoloris HFVI Monitor
Common Name:	Heart Rate Variability Monitor
Classification Name:	Electrocardiograph
Classification Regulation:	21 CFR §870.2340
Product Code:	DPS

Substantially Equivalent Devices:	*New Mdoloris Model*	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
	Mdoloris Medical Systems SAS HFVI Monitor	K071168	DyAnsys, Inc. The Portable ANSiscope™

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Device Description: The Mdoloris Medical Systems SAS (Mdoloris) HFVI Monitor is a heart rate variability monitor intended for use in a medical environment and under the direct supervision of a licensed healthcare practitioner or by personnel specifically trained for its use. The HFVI Sensor acquires electrocardiographic (ECG) signals from the patient, and the Mdoloris HFVI Monitor analyzes the ECG information using a proprietary algorithm that results in the calculation of the High Frequency Variability Index (HFVI).

The HFVI is a measure of heart rate variability (HRV), and has a value between 0 and 100.

It is intended for use on adult and pediatric patients.

Intended Use: The Mdoloris Medical Systems SAS HFVI Monitor is intended to acquire, display, and analyze electrocardiographic information and to measure-heart rate variability (HRV). These and other measurements are not intended for any specific clinical diagnosis. The clinical significance of HRV and other parameters must be determined by the physician.

Technology Comparison: The Mdoloris HFVI Monitor employs the same technological characteristics as the predicate device.

Characteristic	*Predicate Device*	*Proposed Device*
Displayed Parameters	Real-time ECG waveform Real-time heart rate Real-time sympathovagal balANS (from -50 to 50) Real-time sympathetic ANS_i index (from -50 to 50) Real-time parasympathetic ANS_i index (from -50 to 50) ECG lead selection Dysfunction Static balANS Percent of dysfunction	ECG graph (not for diagnosis) Instantaneous HFVI Medium trend HFVI HFVI graph Filtered RR Series Energy Index value Signal quality indicator (color indicator of Energy Index)
Number of Electrodes	Three (3) for HRV One (1) for grounding Chest lead for ECG functionality	Three (3) for HRV

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Characteristic	*Predicate Device*	*Proposed Device*
Type of Analysis	Separation of sympathetic and parasympathetic components of the Autonomic Nervous System (ANS) by scale covariance approach Sympathetic response is real part of complex wave function Parasympathetic response is imaginary part of complex wave function	R-R series artifacts removal R-R series re-sampling Normalization of the signal

Summary of Performance Testing:

Software

The Mdoloris HFVI Monitor software was designed and developed according to a robust software development process, and were rigorously verified and validated. Software information is provided in accordance with internal requirements and the following guidance documents:

- *FDA guidance: The content of premarket submissions for software contained in medical devices, 11 May 05;*
- *FDA guidance: Off-the-shelf software use in medical devices, 09 Sep 99; and*
- *FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02.*

Test results indicate that the Mdoloris HFVI Monitor complies with its predetermined specifications and the guidance documents.

Electrical Safety

The Mdoloris HFVI Monitor was tested for patient safety in accordance with the following standards:

- *IEC 60601-1: 2005, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

Test results indicated that the Mdoloris HFVI Monitor complies with the applicable Standards.

Electromagnetic Compatibility

The Mdoloris HFVI Monitor was tested for EMC in accordance with the following standard:

- *IEC 60601-1-2: 2007, Medical Electrical Equipment, Part 1: Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility-Requirements and Tests.*

Test results indicated that the Mdoloris HFVI Monitor complies with the applicable Standard.

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Performance Testing – Bench

The Mdoloris HFVI Monitor was tested for performance in accordance with internal requirements and the following standard.

- *AAMI EC12: 2000, Disposable ECG Electrodes;*
- *IEC 62366: 2007, Medical devices – Application of usability engineering to medical devices; and*
- *ISTA Procedure 2A, Partial simulation performance test procedure – Packaged-products 150 lb (68 kg) or less.*

Test results indicated that the Mdoloris HFVI Monitor complies with internal requirements and the applicable Standard.

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of the device modifications made to the Mdoloris HFVI Monitor. The results of these activities demonstrate that the Mdoloris HFVI Monitor is as safe, as effective, and performs as well as or better than the predicate device.

Therefore, the Mdoloris HFVI Monitor is considered substantially equivalent to the predicate device.