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Stryker's Reprocessed OxiMax™ Adt and Neo Pulse Oximeter Sensors (MAX-A, MAX-N): non-motion clinical study

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Keywords

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Clinical study purpose

Pulse oximeter sensors are medical devices that are routinely used for non-invasive measurement of arterial blood oxygen saturation and pulse rate. Pulse oximeters function by transmitting light at known wavelengths though blood, measuring the spectrum of absorbed and transmitted light, to determine blood oxygen saturation. As part of the U.S. Food and Drug Administration (FDA) guidance on pulse oximeters, manufacturers are expected to collect data from devices tested on the indicated population to claim an intended use.

Stryker's Sustainability Solutions business is the third largest, global manufacturer of pulse oximeter sensors. As part of the reprocessing and manufacturing process, we collect used devices from hospitals, disassemble and clean them, replace required components, and test the functional performance of the devices to ensure they meet or exceed regulatory requirements and the expectations of our customers. All class II reprocessed product lines are required to obtain new 510(k) clearance, thus demonstrating device substantial equivalence, safety and efficacy.

Through non-motion clinical testing, our devices were rigorously tested and found to exceed FDA requirements across all measures.

Study method

To demonstrate device efficacy, Stryker performed non-motion clinical testing as described in the FDA's Guidance Pulse Oximeters – Premarket Notification Submissions [510(k)s]: Guidance for Industry and Food and Drug Administration Staff (2013) and ISO 80601-2-61:2011 Medical Electrical Equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment. Clinical testing was performed in partnership with the Hypoxia Lab at the University of California, San Francisco.

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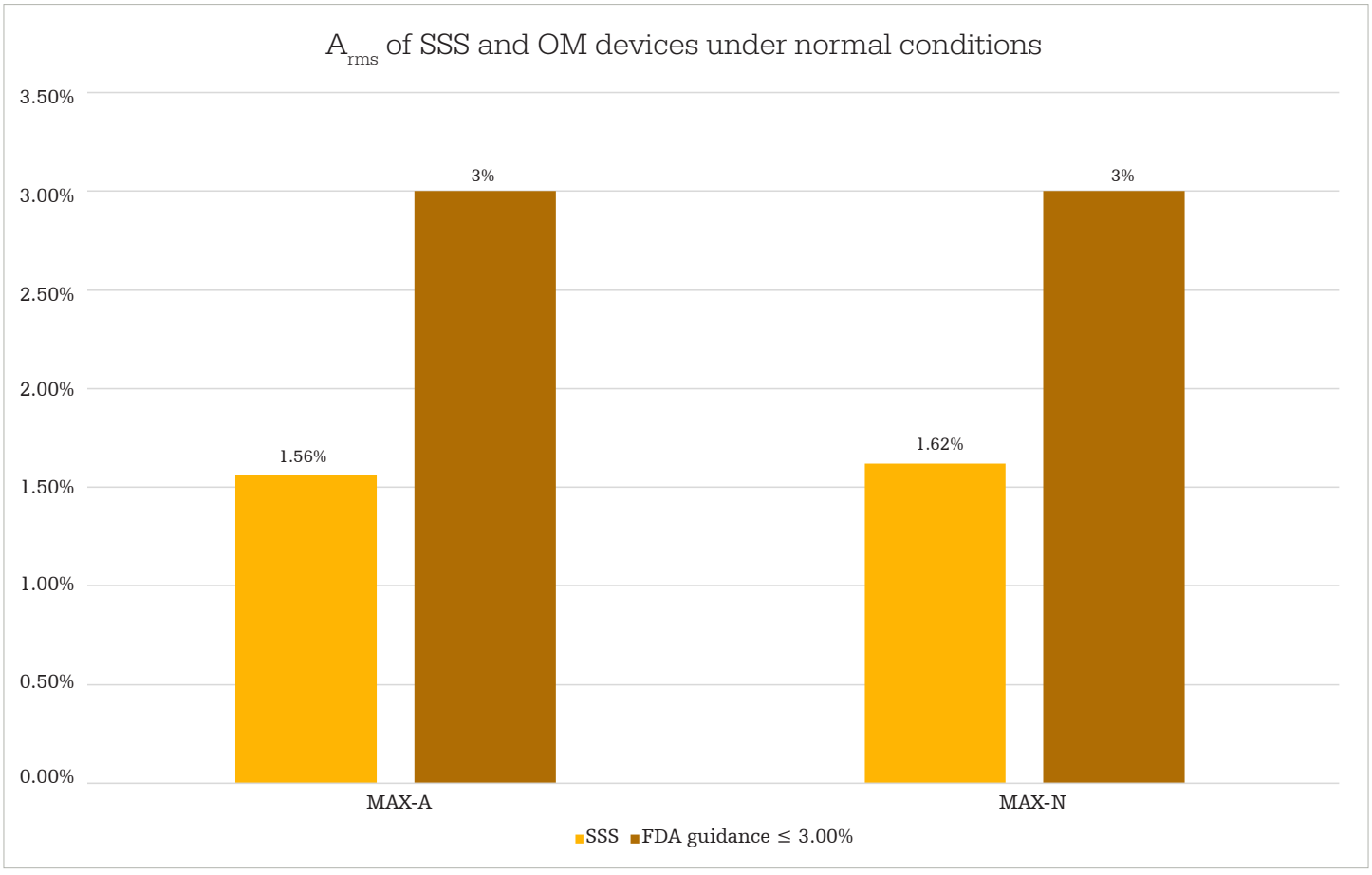
As part of this clinical testing, a clinical study was performed, consisting of 12 healthy adult volunteer participants. The participants represented a range of ages, heights, weights, genders and skin pigmentation to ensure a representative study population to the U.S. demographic. Recent studies, such as the one published by Sjoding et. al in the New England Journal of Medicine, present the potential that patient skin pigmentation may decrease the accuracy of pulse oximeters. Because we have tested our reprocessed devices on participants with a wide range of skin pigmentations, we are confident that they will meet the needs of all our customers.

During each study, air intake of the participant was carefully controlled and monitored by an anesthesiologist to obtain SpO_2 data in the range of 70% to 100%. This data was compared to data collected using an arterial blood gas analyzer to determine the average root mean square difference (A_{rms}).

Results

Stryker's Reprocessed OxiMax Pulse Oximeter Sensors (MAX-A, MAX-N) meet and exceed the FDA requirements of an A_{rms} of ≤ 3% across the 70-100%. This was achieved by collecting 200 or more data points from the FDA required 10 or more subjects, 15% of which were darkly pigmented.

See below for figures supporting this claim.



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Conclusion

As indicated by the 510(k) clearance, the FDA has determined that our reprocessed OxiMax MAX-A and MAX-N pulse oximeter sensors are substantially equivalent, or as safe and effective, as new, unused sensors originally manufactured by Nellcor.

References

1. Pulse Oximeters – Premarket Notification Submissions [510(k)s]: Guidance for Industry and Food and Drug Administration Staff (2013)

2. ISO 80601-2-61:2011 Medical Electrical Equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

3. Internal Stryker Clinical Research Document CRD10303 Rev A, Hypoxia Clinical Study Report for Reprocessed Masimo and Nellcor™ VHP Pulse Oximeters

4. Sjoding, Michael W, et al. "Racial Bias in Pulse Oximetry Measurement." New England Journal of Medicine, vol. 385, no. 26, 17 Dec. 2020, https://doi.org/10.1056/nejmx210003

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