510(K) SUMMARY

NBM-200 PULSE OXIMETER AND HEMOGLOBIN MONITOR

510(k) Number BK190322

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Trade Name: NBM-200 Pulse Oximeter and Hemoglobin Monitor

Device Common Name: Pulse Oximeter

Regulation Number: 21 CFR § 864.7500

Regulation Name: Whole blood hemoglobin assays

Product Code: QGU

Predicate Device: HemoCue Hb 301 system (BK060048) manufactured by HemoCue Inc.

Device Description:

The NBM-200 is a portable Hemoglobin and oximetry monitor, based on occlusion spectroscopy technology, for non-invasive spot checking of hemoglobin (Hb), estimated Hematocrit (Hct), SpO2 and pulse rate. These parameters can be displayed periodically for patient monitoring.

The NBM-200 includes a reusable ring-shaped sensor probe that fits on the patient's finger, and a portable desktop monitor that calculates and displays the measurement result. The sensor probe consists of a multi-wavelength optical measuring system and inflatable cuff employing pneumatic tissue manipulation. Blood flow in the finger can be briefly occluded and the resulting changes in its optical behavior are analyzed to provide accurate measurements of Hb.

Intended Use / Indication for Use:

The NBM-200 is a portable Hemoglobin and oximetry monitor. It non-invasively spot checks and displays Hemoglobin (Hb), estimated Hematocrit (Hct) values, functional saturation of arterial oxygen hemoglobin (SpO2), and pulse rate (PR). These parameters can be displayed periodically for patient monitoring.

The monitor estimates Hct via a calculation based on the Hb measurement for normal hemoglobin values (11 to 17 g/dL) only and abnormal values will not be displayed. It is intended for use by trained medical personnel, with adult individuals, in non-critical clinical and non-clinical settings, e.g., non-critical settings in hospitals, hospital-type facilities, blood donation settings, mobile environments, clinics, physician offices and ambulatory surgery centers. In this context, non-critical means patient examination settings where continuous monitoring is unnecessary. Non-critical environments exclude, for example, intensive care units.

Technological Characteristics

The NBM-200 includes a portable monitor and a cable-connected finger sensor with inflatable cuffs employing pneumatic tissue manipulation and an optical measuring system. The sensor consists of a multi-wavelength light source, a photodetector and a radial finger cuff for temporarily controlled tissue pressure. The measurement process is based on successive occlusion and release cycles and on the occlusion spectroscopy algorithm for the calculation of blood parameters.

Test Data

The NBM-200 device has been subjected to extensive testing before its release to ensure that it complies with the desired specifications and safety and performance standards. The tests included testing of its electrical functionality and safety, EMC, software and functionality under various environmental conditions.

Additional testing ensured that the device meets its performance specifications for oximetry (SpO2 and pulse rate) measurements with an adequate safety profile.

Clinical Data

A clinical study was performed in order to validate the performance of OrSense's NBM-200 Pulse Oximeter and Hemoglobin Monitor device in a blood donation environment.

The study evaluated healthy volunteers who were active donors or candidates for donation of blood or aphaeresis products, and compared hemoglobin (Hb) values obtained by 3 methods: The NBM-200 system; HemoCue Hb 301 device based on finger sticks with capillary blood that is FDA-cleared (BK060048) for use in blood banks; and Sysmex XE-2100 laboratory blood analyzer using venous blood samples that is cleared by FDA (K992875). The NBM-200 was used in Hb parameter mode for the performance testing.

Data from 355 subjects at 3 sites were available for the comparison analyses required, 134 females and 221 males. Hemoglobin values ranged between 8.5 and 17.1g/dL. The precision study included 14 donors in the repeatability part and 18 in the reproducibility part. In addition to the accuracy evaluation, the comparison study compared the anemia detection by the NBM and HemoCue against the lab determination. Subjects are deferred from donating blood if anemic, with anemia defined as a hemoglobin level less than 12.5 g/dL for females or less than 13 g/dL for males.

Main results:

- The overall accuracy of the NBM-200 is -0.029g/dL ± 0.99g/dL and the overall relative accuracy is -0.0478% ± 7.59%.
- The overall accuracy of the HemoCue is 0.481g/dL ± 0.631g/dL and the relative accuracy is 3.46% ± 4.62%.
- NBM device has a higher repeatability with a smaller CV than that of the HemoCue (2.2% vs. 4.6%).
- NBM between device, operator and finger reproducibility CVs for each subject are all less than 3.66%
- The deferral rate by the lab method is 28.45%, by the NBM is 27.89% and by the HemoCue is 21.13%. However, among the 99 subjects deferred by NBM, 28 were

eligible donors by the lab method and among the 75 subjects deferred by HemoCue, only 6 were eligible by the lab method.

- Sensitivity of the NBM-200 in anemia detection, compared against the diagnosis of the lab, is 70.3% while that of HemoCue is 68.32%.
- Specificity of the NBM-200 in anemia detection, compared against the diagnosis of the lab, is 88.98% versus that of HemoCue which is 97.64%.
- No adverse events or subject discontinuation were reported during the study.

Table 1 shows a comparison of the sensitivity of the NBM-200 and HemoCue in the detection of anemic subjects (diagnosed by lab) for males, females and overall. A "positive" anemia result is defined as detection of anemia and deferral from blood donation, while a "negative result" means no anemia and eligibility for donation.

Table 1: Sensitivity (anemia detected by Lab)

Males (n=39)		HemoCue		
		Positive	Negative	Total
NBM-200	Positive	18	5	23
	Negative	5	11	16
	Total	23	16	39
Females (n=62)		HemoCue		
		Positive	Negative	Total
NBM-200	Positive	39	9	48
	Negative	7	7	14
	Total	46	16	62
Overall (n=101)		HemoCue		
		Positive	Negative	Total
NBM-200	Positive	57	14	71
	Negative	12	18	30
	Total	69	32	101

Table 2 shows a comparison of the specificity of the NBM-200 and HemoCue in the detection of non-anemic subjects for males, females and overall.

Table 2: Specificity (anemia not detected by Lab)

Males (n=182)		HemoCue		
		Positive	Negative	Total
NBM-200	Positive	0	12	12
	Negative	5	165	170
	Total	5	177	182

Females (n=72)		HemoCue		
		Positive	Negative	Total
NBM-200	Positive	0	16	16
	Negative	1	55	56
	Total	1	71	72

Overall (n=254)		HemoCue		
		Positive	Negative	Total
NBM-200	Positive	0	28	28
	Negative	6	220	226
	Total	6	248	254

Table 3 shows a comparison of the detection of subjects as deferred or eligible for donation by the NBM-200 and HemoCue in the repeatability study.

Table 3: Deferrals (anemia detection) in the repeatability study

Gender	NBM200				HemoCue301			
	# of replicates	Mean Hb [g/dL]	Eligible	Deferred	# of replicates*	Mean Hb [g/dL]	Eligible	Deferred
Female	6	14.15	6	0	6	14.92	6	0
Male	6	14.57	6	0	6	14.93	6	0
Female	6	9.60	0	6	6	10.37	0	6
Female	6	12.58	5	1	6	12.55	3	3
Female	6	12.62	5	1	6	14.10	6	0
Male	6	14.12	6	0	6	16.27	6	0
Male	6	14.23	6	0	6	13.87	6	0
Male	6	12.97	3	3	6	14.03	6	0
Female	6	13.57	6	0	6	12.28	2	4
Female	6	12.53	3	3	6	13.25	6	0
Female	6	12.60	3	3	6	11.95	1	5
Female	6	12.72	5	1	6	12.60	4	2
Male	6	14.47	6	0	6	13.77	5	1
Female	6	13.88	6	0	6	13.08	6	0

*conducted with separate finger-prick for each test/replicate

Table 4 shows the NBM-200's detection of subjects as deferred or eligible for donation in the reproducibility study.

Table 4: Deferrals (anemia detection) in the reproducibility study

Gender	Site	NBM200			
		# of replicates	Mean Hb [g/dL]	Eligible	Deferred
Female	Site 1	16	12.91	15	1
Female	Site 1	15	13.75	15	0
Male	Site 1	16	13.85	16	0
Female	Site 1	16	12.98	16	0
Male	Site 1	16	15.25	16	0
Female	Site 1	15	11.99	0	15
Male	Site 1	16	12.84	9	7
Male	Site 1	16	14.43	16	0
Female	Site 2	11	13.91	11	0
Male	Site 2	10	15.41	10	0
Female	Site 2	12	12.75	9	3
Female	Site 2	11	13.26	11	0
Female	Site 2	15	13.11	15	0
Male	Site 2	16	14.00	16	0
Male	Site 2	13	15.29	13	0
Male	Site 2	16	13.91	16	0
Female	Site 2	16	13.24	16	0
Female	Site 2	16	14.38	16	0

The following clinical data were relied upon for the previous NBM-200 clearance (K142209), and previously submitted to FDA in K091564 and K124041.

1. Study for assessment of Oximetry accuracy as submitted for K091564.
2. Studies for assessment of hemoglobin accuracy and precision as submitted for K124041.

Substantial Equivalence

The proposed NBM-200 has the same intended use as the predicate HemoCue Hb 301, *i.e.*, providing hemoglobin values, including in blood donation settings. In both the NBM-200 and the predicate Hb 301 the measurement of hemoglobin is based on spectroscopy, i.e., transmission of light through the blood and detection of attenuated intensity.

The NBM-200 and the predicate Hb 301 rely on different technologies to isolate the effect of blood from other tissue components: the NBM manipulates the blood volume via occlusion, while the HemoCue device uses blood extracted into a cuvette. The proposed NBM-200 is technologically identical to the reference NBM-200 cleared by CDRH (K142209), except for minor software updates.

Due to the differences in technological characteristics between the proposed NBM-200 and the predicate Hb 301, OrSense provided clinical data to compare the devices' performance. The data show that the different technological characteristics do not raise different questions of safety or effectiveness, and that the proposed NBM-200 is at least as safe and effective as the predicate Hb301.

As a result, the NBM-200 Pulse Oximeter and Hemoglobin Monitor device is substantially equivalent to the 510(k)-cleared HemoCue Hb 301 system (BK060048) manufactured by HemoCue Inc.