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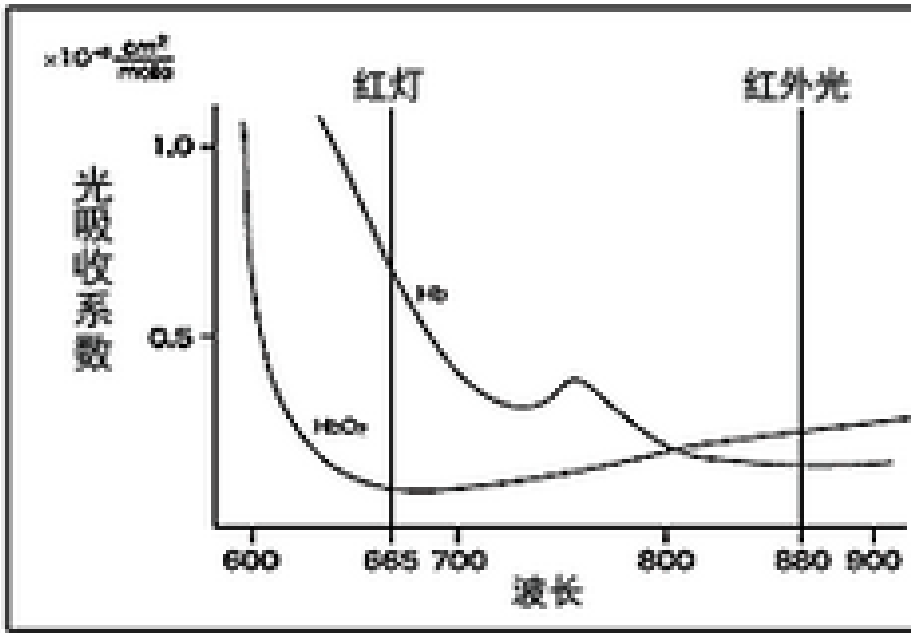
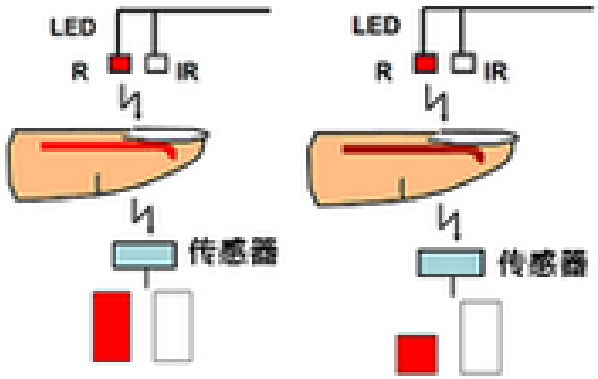
About SpO2 accuracy with dark skin

Measuring principle of oximeter

The graph on the right is called the absorbance curve, which shows what kind of light can be absorbed in a large amount of hemoglobin (HbO2) that binds to oxygen and hemoglobin (Hb) that releases oxygen. The color is represented by the wavelength on the horizontal axis. The two curves in the figure indicate which wavelengths HbO2 and Hb can absorb in large quantities, and which wavelengths are difficult to absorb. It means that the further below the line, the less likely it is to absorb its wavelength (good passability).



The hemoglobin bound to oxygen is red, because the red color is not absorbed and passes through. That is, the absorbance of red is low. On the other hand, the hemoglobin after the release of oxygen becomes dark. This is due to the large amount of light absorption. After the red (R) is irradiated to the blood, if hemoglobin is more combined with oxygen, a corresponding large amount of light passes through the finger, so the amount of light received by the sensor increases. Regardless of whether hemoglobin is combined with oxygen or not, infrared light (IR) will pass through the blood without much change. If HbO2 increases and Hb decreases, the red light (R) received by the sensor will increase, while the infrared light (IR) will not change much. On the contrary, the red light is reduced, and the infrared light still does not change much. In other words, if you know the ratio of R/IR received by the sensor, you can clarify the ratio of HbO2 to Hb, that is, oxygen saturation.



Factors affecting the performance of oximeter

Inaccurate measurements may be caused by:

- Significant levels of dysfunctional hemoglobin (such as carbonyl - hemoglobin or methemoglobin).
- Intravascular dyes such as indocyanine green or methylene blue.
- High ambient light. Shield the sensor area if necessary.
- Excessive patient movement.
- High-frequency electrosurgical interference and defibrillators.
- Venous pulsations.
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
- The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
- The patient is in cardiac arrest or is in shock.
- Fingernail polish or false fingernails.
- Weak pulse quality (low perfusion).
- Low hemoglobin.

ChoiceMMed Oximeter

According to FDA's guidance information, we need to submit the clinical test report for the oximeter which needs a 510K number.

4.1.1 *In vivo* testing for SpO_2 accuracy under laboratory conditions

We recommend you follow Clause 201.12.1.101.2 and Annex EE.2 of ISO 80601-2-61:2011 *Procedure for invasive laboratory testing on healthy volunteers,* or equivalent method to validate the SpO_2 accuracy specifications of your pulse oximeter system by comparing each value from your system and a simultaneous value from co-oximetry of an arterial blood sample. We recommend you submit a detailed clinical report for this testing. Your report should describe the device configuration tested and include the following:

- test apparatus used, including means for arterial catheterization and blood sampling, means for recording SpO_2 values, and means for delivering medical grade oxygen-nitrogen mixtures of varying fractional inspired oxygen (FiO_2) levels;
- inclusion and exclusion criteria;
- number of subjects;
- number of samples taken per subject;
- specific conditions of testing, including laboratory conditions, subject motion, low pulse amplitude;
- type and frequency of motion for testing under motion conditions, if applicable;
- criteria and methods for determining stability of reference arterial blood oxygen saturation (SaO_2) at the pulse oximeter sensor site;
- desaturation profile, including target saturation plateaus and ranges; and
- formula used for determination of root mean square difference (A_{rms}). (See Clause 201.12.1.101.2.2 of ISO 80601-2-61:2011 for recommended formula.)

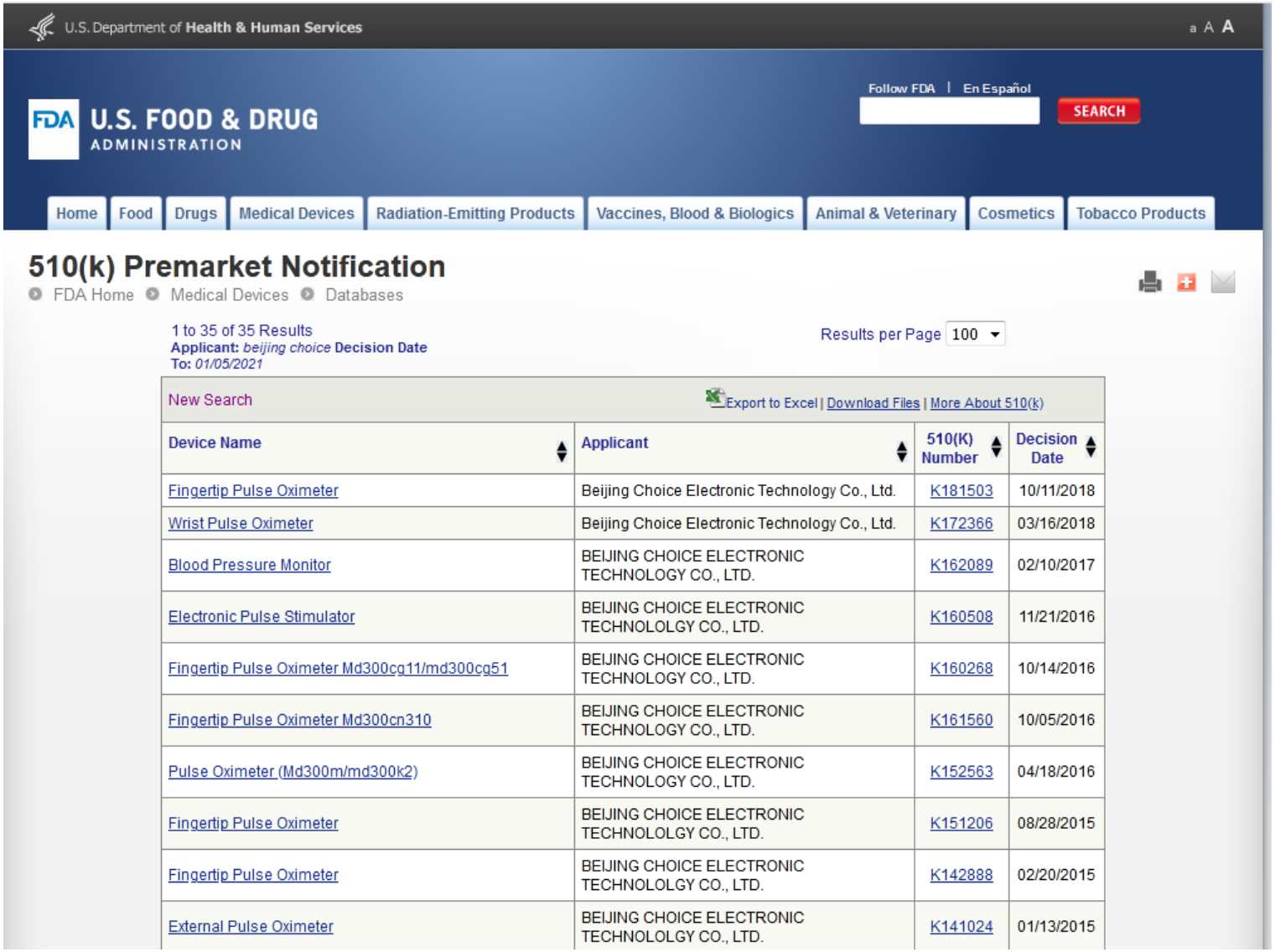
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/pulse-oximeters-premarket-notification-submissions-510ks-guidance-industry-and-food-and-drug

When ChoiceMMed submitted the 510K application for our oximeters, we provided the clinical test report; there are 4 participants with dark skin. And the result shows our oximeters are with the required measurement accuracy. If necessary, we can provide the corresponding clinical test report excerpts.

The study was conducted in accordance to ISO 14155-1, -2, ISO 9919:2005, EN ISO 9919:2009, BS EN ISO 80601-2-61:2011, and the FDA Guidance Document for Pulse Oximeters.

There were no adverse events during the study. The subject demographics included a total of 12 subjects, 6 females and 6 males. The subject ages ranged from 21 to 28 years. The subject weights ranged from 46 to 74kg. The skin tones included in the study were as follows: 4 subject with very dark pigmentation, 1 subjects with very light pigmentation. The remaining subjects with light skin tones of China origins. Subject #5 (male, light skin tones of China origins) and #12 (male, very dark pigmentation skin tones of African origins) too nervous, causing the heart rate more than 120 bpm. Based on the ECG sinus rhythm test result, declined from the study.

Compared to Reference CO-Oximeter, Functional SaO2 Apr 6-8, 2012	**Functional SaO2 70-100% A_{RMS}**	**# of Points**	**Specification 70-100% A_{RMS}**
MD300C2 Fingertip Pulse Oximeter	1.69	207	**Pass A_{RMS} of 3**



U.S. Department of Health & Human Services

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1 to 35 of 35 Results
Applicant: *beijing choice* **Decision Date**
To: *01/05/2021*

Results per Page 100

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Device Name	Applicant	510(K) Number	Decision Date
Fingertip Pulse Oximeter	Beijing Choice Electronic Technology Co., Ltd.	K181503	10/11/2018
Wrist Pulse Oximeter	Beijing Choice Electronic Technology Co., Ltd.	K172366	03/16/2018
Blood Pressure Monitor	BEIJING CHOICE ELECTRONIC TECHNOLOGY CO., LTD.	K162089	02/10/2017
Electronic Pulse Stimulator	BEIJING CHOICE ELECTRONIC TECHNOLOLGY CO., LTD.	K160508	11/21/2016
Fingertip Pulse Oximeter Md300cg11/md300cg51	BEIJING CHOICE ELECTRONIC TECHNOLOGY CO., LTD.	K160268	10/14/2016
Fingertip Pulse Oximeter Md300cn310	BEIJING CHOICE ELECTRONIC TECHNOLOGY CO., LTD.	K161560	10/05/2016
Pulse Oximeter (Md300m/md300k2)	BEIJING CHOICE ELECTRONIC TECHNOLOGY CO., LTD.	K152563	04/18/2016
Fingertip Pulse Oximeter	BEIJING CHOICE ELECTRONIC TECHNOLOLGY CO., LTD.	K151206	08/28/2015
Fingertip Pulse Oximeter	BEIJING CHOICE ELECTRONIC TECHNOLOLGY CO., LTD.	K142888	02/20/2015
External Pulse Oximeter	BEIJING CHOICE ELECTRONIC TECHNOLOLGY CO., LTD.	K141024	01/13/2015

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?start_search=1&Center=&Panel=&ProductCode=&KNumber=&Applicant=beijing%20choice&DeviceName=&Type=&ThirdPartyReviewed=&ClinicalTrials=&Decision=&DecisionDateFrom=&DecisionDateTo=01%2F05%2F2021&IVDProducts=&Redact510K=&CombinationProducts=&ZNumber=&PAGENUM=100

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Compliance to ISO and IEC standard

- Safety: IEC 60601-1
- Specific standard of Pulse Oximeter: ISO 80601-2-61
- Software: IEC 62304
- Risk management: ISO 14971
- EMC: IEC 60601-1-2
- Biocompatibility: ISO10993-1 , ISO10993-5, ISO10993-10
- Usability: IEC 60601-1-6
- Data transfer: RED、FCC

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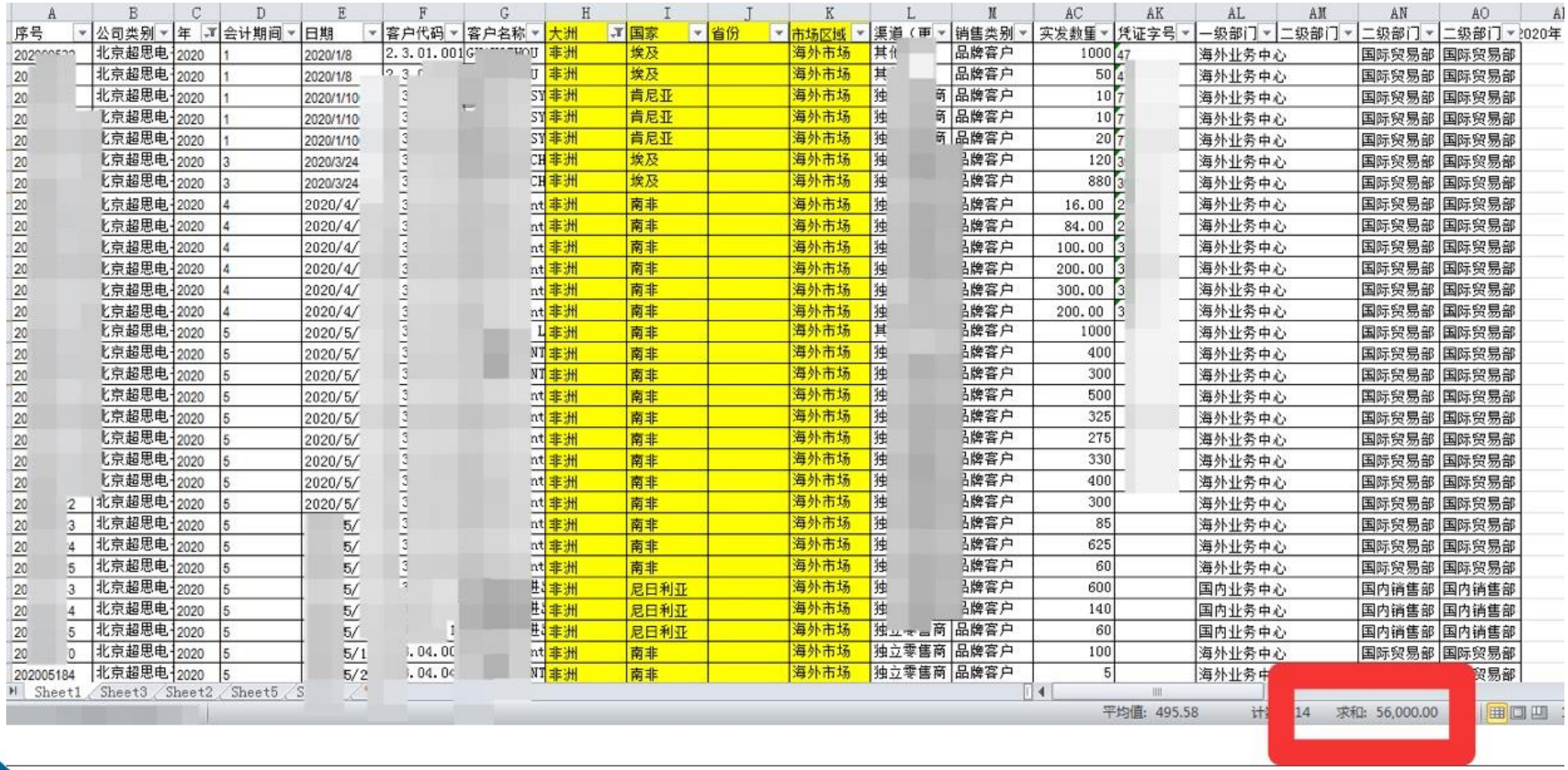
According to the sales data in 2020, ChoiceMMed has supplied 56,000 oximeters to the African market. And the complaints about measurement accuracy are zero.



序号	公司类别	年	会计期间	日期	客户代码	客户名称	大洲	国家	省份	市场区域	渠道	销售类别	实发数量	凭证字号	一级部门	二级部门	二级部门	二级部门
202	北京超思电	2020	1	2020/1/8	2.3.01.001	G	非洲	埃及		海外市场	其	品牌客户	1000	47	海外业务中心		国际贸易部	国际贸易部
20	北京超思电	2020	1	2020/1/8		U	非洲	埃及		海外市场	其	品牌客户	50	4	海外业务中心		国际贸易部	国际贸易部
20	北京超思电	2020	1	2020/1/10		SY	非洲	肯尼亚		海外市场	独	品牌客户	10	7	海外业务中心		国际贸易部	国际贸易部
20	北京超思电	2020	1	2020/1/10		SY	非洲	肯尼亚		海外市场	独	品牌客户	10	7	海外业务中心		国际贸易部	国际贸易部
20	北京超思电	2020	1	2020/1/10		SY	非洲	肯尼亚		海外市场	独	品牌客户	20	7	海外业务中心		国际贸易部	国际贸易部
20	北京超思电	2020	3	2020/3/24		CH	非洲	埃及		海外市场	独	品牌客户	120	3	海外业务中心		国际贸易部	国际贸易部
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20 5	北京超思电	2020	5	5/		nt	非洲	南非		海外市场	独	品牌客户	60		海外业务中心		国际贸易部	国际贸易部
20 3	北京超思电	2020	5	5/			非洲	尼日利亚		海外市场	独	品牌客户	600		国内业务中心		国内销售部	国内销售部
20 4	北京超思电	2020	5	5/			非洲	尼日利亚		海外市场	独	品牌客户	140		国内业务中心		国内销售部	国内销售部
20 5	北京超思电	2020	5	5/			非洲	尼日利亚		海外市场	独立零售商	品牌客户	60		国内业务中心		国内销售部	国内销售部
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Sheet1 Sheet3 Sheet2 Sheet5

平均值: 495.58 计 14 求和: 56,000.00


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