

JUL 19 2013

iHealth cloud FDA 510(k) Files

510(k) Summary

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

1.0 submitter's information

Name: Andon Health Co., Ltd.
Address: No 3, Jinping Road, Ya' an street TIANJIN,300193
Phone number: 86-22-60526161
Fax number: 86-22-6052 6162
Contact: Yi Liu
Date of Application: 4/24/2013

2.0 Device information

Trade name: iHealth cloud
Common name: Patient Vital Signs Monitor Viewing Station
Classification name: Patient Vital Signs Monitor Viewing Station

3.0 Classification

Production code: DXN, NBW, MNW
Regulation number: 21 CFR 870.2770, 21 CFR 862.1345, 21 CFR 870.1130
Classification: II
Panel: 870 Cardiovascular, 862 Clinical Chemistry

4.0 Predict device information

Manufacturer: Watermark Medical
Device: Connected Care Clinical Application
510(k) number: K120320

5.0 Device description

iHealth cloud is a cloud based, web software system. It is accessed from commercially available PC systems with a web browser and minimum performance specifications consistent with typical PC hardware and equipment specifications. iHealth cloud accepts data both electronically as well as from manually input.

iHealth cloud is a medical device data system that displays and analyzes data received from iHealth home monitoring devices as well as manually input data. iHealth home monitoring devices include the apps and the device, such as KD-931, KD-936, KD-972 and Scale HS3

and HS5, AG-631, AG-632, AM3, PO3 and iHealth MyVitals.

6.0 Intended use

IHealth cloud's intended use is to retrospectively display and analyze related medical data. The Web Application is not intended for emergency use or real-time monitoring.

7.0 Performance summary

The software validation results demonstrated that the Clinical Application was in compliance with the guidelines and standards referenced in the FDA reviewer's guides and that it performed within its specifications and functional requirements for software.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of FDA regarding Medical device software.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service



July 19, 2013

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Andon Health Co., Ltd
Yi Liu
President
No. 3 Jinping Road, Ya' An Street
Tianjin, China 300193

Re: K131203
Trade/Device Name: IHealth Cloud
Regulation Number: 21 CFR 870.2770
Regulation Name: Patient Vital Signs Monitor Viewing Station
Regulatory Class: Class II
Product Code: DXN, NBW, MNW
Dated: May 20, 2013
Received: May 30, 2013

Dear Yi Liu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Yi Liu

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Owen P. Faris -S

for
Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Ihealth Cloud FDA 510(k) Files

K131203

Indication for Use

510(k) Number (if known):

Device Name: Ihealth Cloud

Indication For Use:

IHealth cloud's intended use is to retrospectively display and analyze related medical data. The Web Application is not intended for emergency use or real-time monitoring.

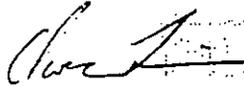
Prescription Use Yes
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use Yes
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



Digitally signed by Owen P. Faris -S
Date: 2013.07.19 16:15:42 -04'00'

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) _____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service



July 19, 2013

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Andon Health Co., Ltd
Yi Liu
President
No. 3 Jinping Road, Ya' An Street
Tianjin, China 300193

Re: K131203
Trade/Device Name: IHealth Cloud
Regulation Number: 21 CFR 870.2770
Regulation Name: Patient Vital Signs Monitor Viewing Station
Regulatory Class: Class II
Product Code: DXN, NBW, MNW
Dated: May 20, 2013
Received: May 30, 2013

Dear Yi Liu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Yi Liu

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Owen P. Faris -S

for
Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Ihealth Cloud FDA 510(k) Files

K131203

Indication for Use

510(k) Number (if known):

Device Name: Ihealth Cloud

Indication For Use:

IHealth cloud's intended use is to retrospectively display and analyze related medical data. The Web Application is not intended for emergency use or real-time monitoring.

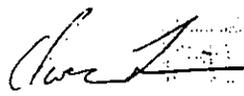
Prescription Use Yes
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use Yes
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

 Digitally signed by Owen P. Faris -S
Date: 2013.07.19 16:15:42 -04'00'

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) _____

Page 1 of _____

iHealth Cloud
FDA 510(k) Document

Version:
Issued Date:
Revised Date:

Andon Health Co., LTD
No 3, Jinping Road, Ya' an street Tianjin, China

Table of content

Item	Page
1 Medical device user fee cover sheet.....	1-1
2 CDRH Premarket Review cover sheet.....	2-1 to 2-5
3 510(k) Cover Letter.....	3-1
4 Statement of Indications for Use.....	4-1
5 510(k) Summary.....	5-1 to 5-2
6 Truthful and accurate statement.....	6-1
7 Class III Summary and certification.....	7-1
8 Financial Certification form 3454.....	8-1
9 Form 3654.....	9-1
10 Executive summary.....	10-1 to 10-2
11 Device description.....	11-1 to 11-2
12 SE comparison.....	12-1 to 12-2
13 Proposed labeling.....	13-1to13-42
14 Sterilization and shelf life.....	14-1
15 Biocompatibility.....	15-1
16 Software validation.....	16-1 to 16-64
17 EMC and Electrical Safety.....	17-1
18 Performance Testing-Bench.....	18-1
19 Performance Testing-Animal.....	19-1
20 Performance Testing-Clinical.....	20-1
21 Form 3674.....	21-1 to 21-2

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CDRH PREMARKET REVIEW SUBMISSION COVER SHEET	Form Approval OMB No. 9010-0120 Expiration Date: August 31, 2010. See OMB Statement on page 5.
--	---

Date of Submission 04/24/2013	User Fee Payment ID Number MD6068244-956733	FDA Submission Document Number (if known)
----------------------------------	--	---

SECTION A TYPE OF SUBMISSION				
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission? Yes No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR			
Company / Institution Name Andon Health Co., Ltd.		Establishment Registration Number (if known)	
Division Name (if applicable)		Phone Number (including area code) (86) 22-6052 6161	
Street Address No 3, Jinping Road, Ya' an street		FAX Number (including area code) (86) 22-60526162	
City Tianjin	State / Province	ZIP/Postal Code 300193	Country China
Contact Name Yi Liu			
Contact Title President		Contact E-mail Address celia4237@yahoo.com.cn	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)			
Company / Institution Name			
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason (specify):		

SECTION D2 REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final		
<input type="checkbox"/> Other Reason (specify):		

SECTION D3 REASON FOR SUBMISSION - 510(k)		
<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input type="checkbox"/> Other Reason (specify):		

SECTION E				ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS				
Product codes of devices to which substantial equivalence is claimed								Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1	DXN	2	NBW	3	MNW	4		
5		6		7		8		

Information on devices to which substantial equivalence is claimed (if known)		
510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K120320	1 Connected Care Clinical Application
2		2
3		3
4		4
5		5
6		6

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
 Data management software

Trade or Proprietary or Model Name for This Device	Model Number
1 IHealth cloud	1
2	2
3	3
4	4
5	5

FDA document numbers of all prior related submissions (regardless of outcome)

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code DXN,NBW,MNW	C.F.R. Section (if applicable) 21 CFR 870.2770, 21 CFR 862.1345, 21 CFR 870.1130	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel 870 Cardiovascular, 862 Clinical Chemistry		

Indications (from labeling)
 IHealth cloud's intended use is to retrospectively display and analyze related medical data. The Web Application is not intended for emergency use or real-time monitoring.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number (if known)

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Andon Health Co., Ltd.		Establishment Registration Number		
Division Name (if applicable)		Phone Number (including area code) (86) 22-6052 6161		
Street Address No 3, Jinping Road, Ya' an street		FAX Number (including area code) (86) 22-60526162		
City Tianjin		State / Province	ZIP/Postal Code 300193	Country
Contact Name Yi Liu		Contact Title President		Contact E-mail Address celia4237@yahoo.com.cn

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name (if applicable)		Phone Number (including area code) ()		
Street Address		FAX Number (including area code) ()		
City		State / Province	ZIP/Postal Code	Country
Contact Name		Contact Title		Contact E-mail Address

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name (if applicable)		Phone Number (including area code) ()		
Street Address		FAX Number (including area code) ()		
City		State / Province	ZIP/Postal Code 300190	Country China
Contact Name		Contact Title		Contact E-mail Address

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					05/08/2012
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
 CDRH (HFZ-342)
 9200 Corporate Blvd.
 Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

510(k) notification Cover Letter

1. Application Type: Traditional 510(K)
2. Common Name: Data Management Software
3. Submitter: Mr. Yi Liu
4. Official contact person authorized by the submitter: Ms. Yang Wang
5. Company name: Andon Health Co., Ltd.
Address: No 3, Jinping Road, Ya' an street TIANJIN,300193
Phone Number: 86-22-60526161
Fax Number: 86-22-6052 6162
6. Device Class: Class II
7. Product Code: DXN, NBW, MNW
8. C.F.R. Section: 21 CFR 870.2770, 21 CFR 862.1345, 21 CFR 870.1130
9. Classification Panel: 870 Cardiovascular, 862 Clinical Chemistry

Design and Use of the Device

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)? ^A		√
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)? ^A	√	
Does the device contain components derived from a tissue or other biologic source?		√
Is the device provided sterile?		√
Is the device intended for single use?		√
Is the device a reprocessed single use device?		√
If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?		√
Does the device contain a biologic?		√
Does the device use software?	√	
Does the submission include clinical information?		√
Is the device implanted?		√

Ihealth Cloud FDA 510(k) Files

Indication for Use

510(k) Number (if known):

Device Name: Ihealth Cloud

-

Indication For Use:

IHealth cloud's intended use is to retrospectively display and analyze related medical data. The Web Application is not intended for emergency use or real-time monitoring.

Prescription Use Yes
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use Yes
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) _____

Page 1 of ____

510(k) Summary

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

1.0 submitter's information

Name: Andon Health Co., Ltd.
Address: No 3, Jinping Road, Ya' an street TIANJIN,300193
Phone number: 86-22-60526161
Fax number: 86-22-6052 6162
Contact: Yi Liu
Date of Application: 4/24/2013

2.0 Device information

Trade name: iHealth cloud
Common name: Patient Vital Signs Monitor Viewing Station
Classification name: Patient Vital Signs Monitor Viewing Station

3.0 Classification

Production code: DXN, NBW, MNW
Regulation number: 21 CFR 870.2770, 21 CFR 862.1345, 21 CFR 870.1130
Classification: II
Panel: 870 Cardiovascular, 862 Clinical Chemistry

4.0 Predict device information

Manufacturer: Watermark Medical
Device: Connected Care Clinical Application
510(k) number: K120320

5.0 Device description

IHealth cloud is a cloud based, web software system. It is accessed from commercially available PC systems with a web browser and minimum performance specifications consistent with typical PC hardware and equipment specifications. IHealth cloud accepts data both electronically as well as from manually input.

IHealth cloud is a medical device data system that displays and analyzes data received from iHealth home monitoring devices as well as manually input data. iHealth home monitoring devices include the apps and the device, such as KD-931, KD-936, KD-972 and Scale HS3

and HS5, AG-631, AG-632, AM3, PO3 and iHealth MyVitals.

6.0 Intended use

IHealth cloud's intended use is to retrospectively display and analyze related medical data. The Web Application is not intended for emergency use or real-time monitoring.

7.0 Performance summary

The software validation results demonstrated that the Clinical Application was in compliance with the guidelines and standards referenced in the FDA reviewer's guides and that it performed within its specifications and functional requirements for software.

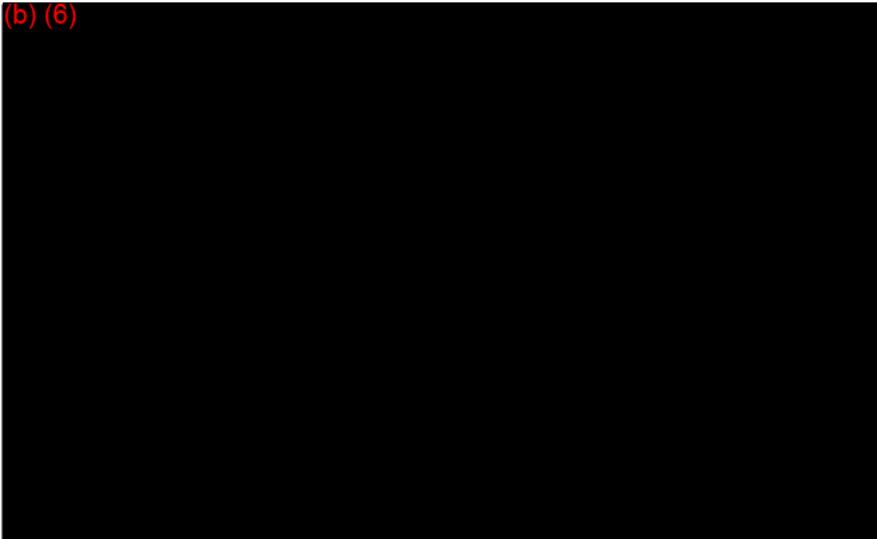
This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of FDA regarding Medical device software.

TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as the President of Board of Directors of Andon Health Co., Ltd. I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(b) (6)



This section does not apply

This section does not apply

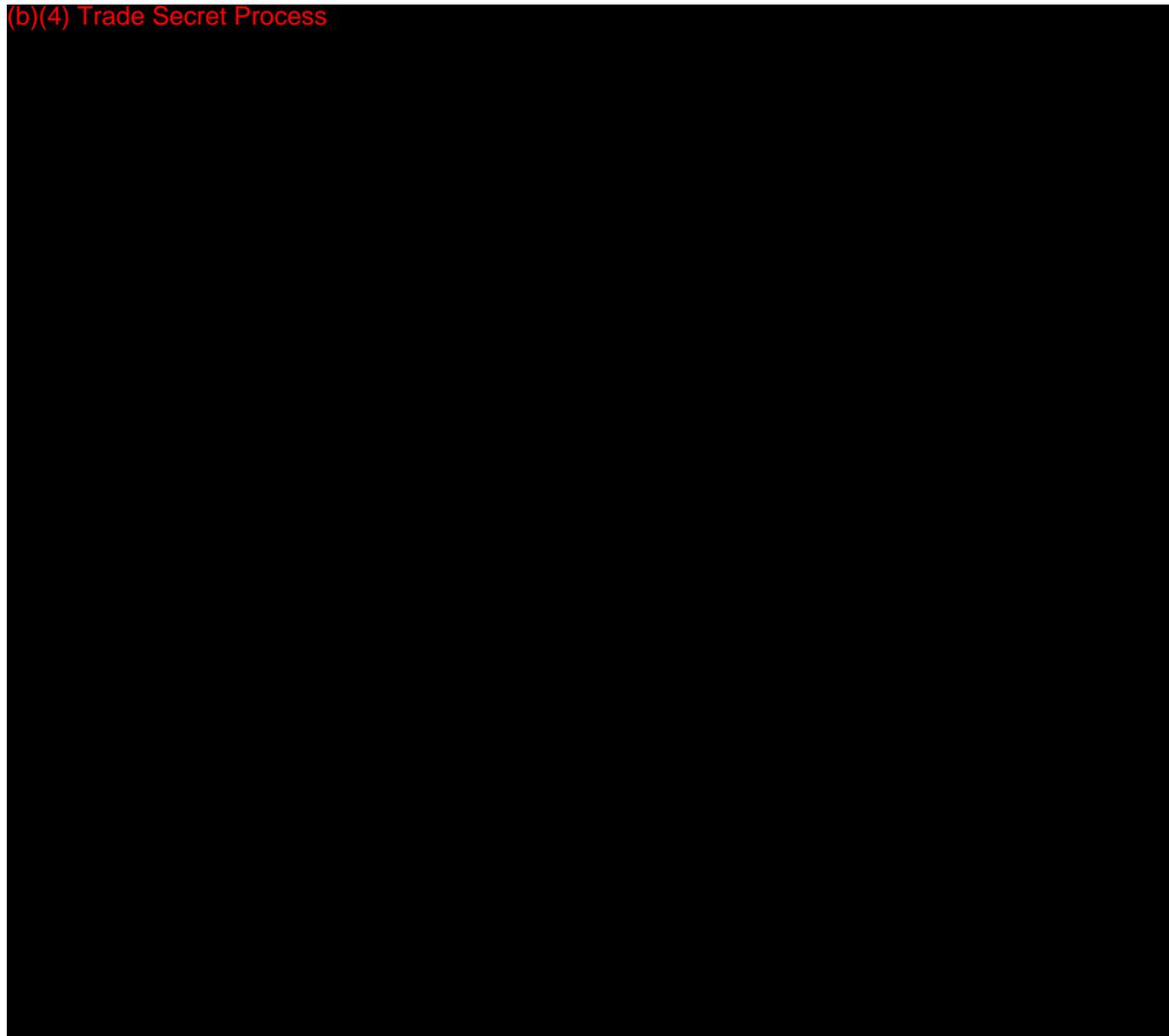
This section does not apply

Executive summary

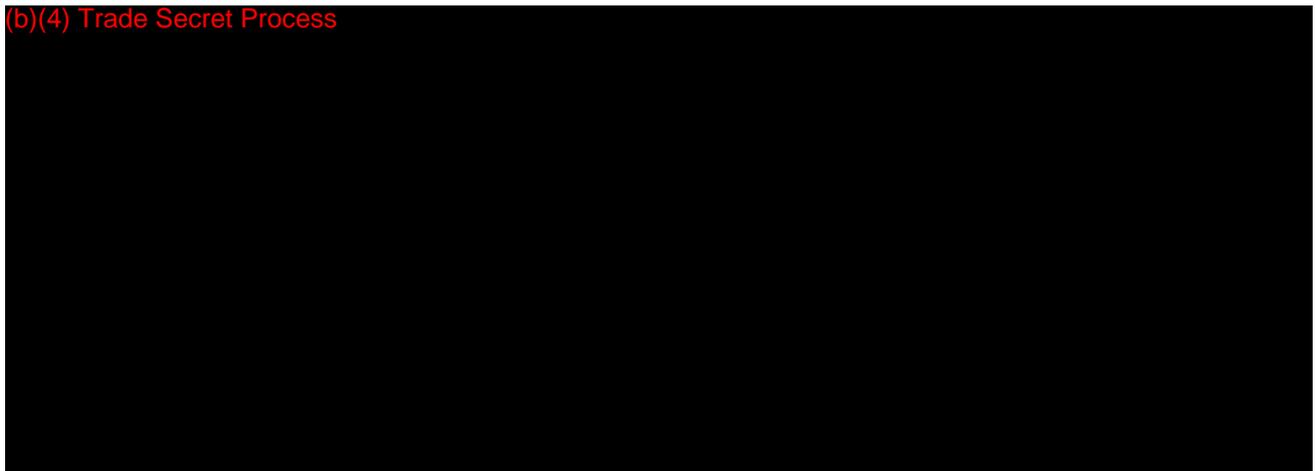
1. A concise summary

IHealth cloud's intended use is to retrospectively display and analyze related medical data. The Web Application is not intended for emergency use or real-time monitoring.

(b)(4) Trade Secret Process



(b)(4) Trade Secret Process



Device description

1 Device name and type

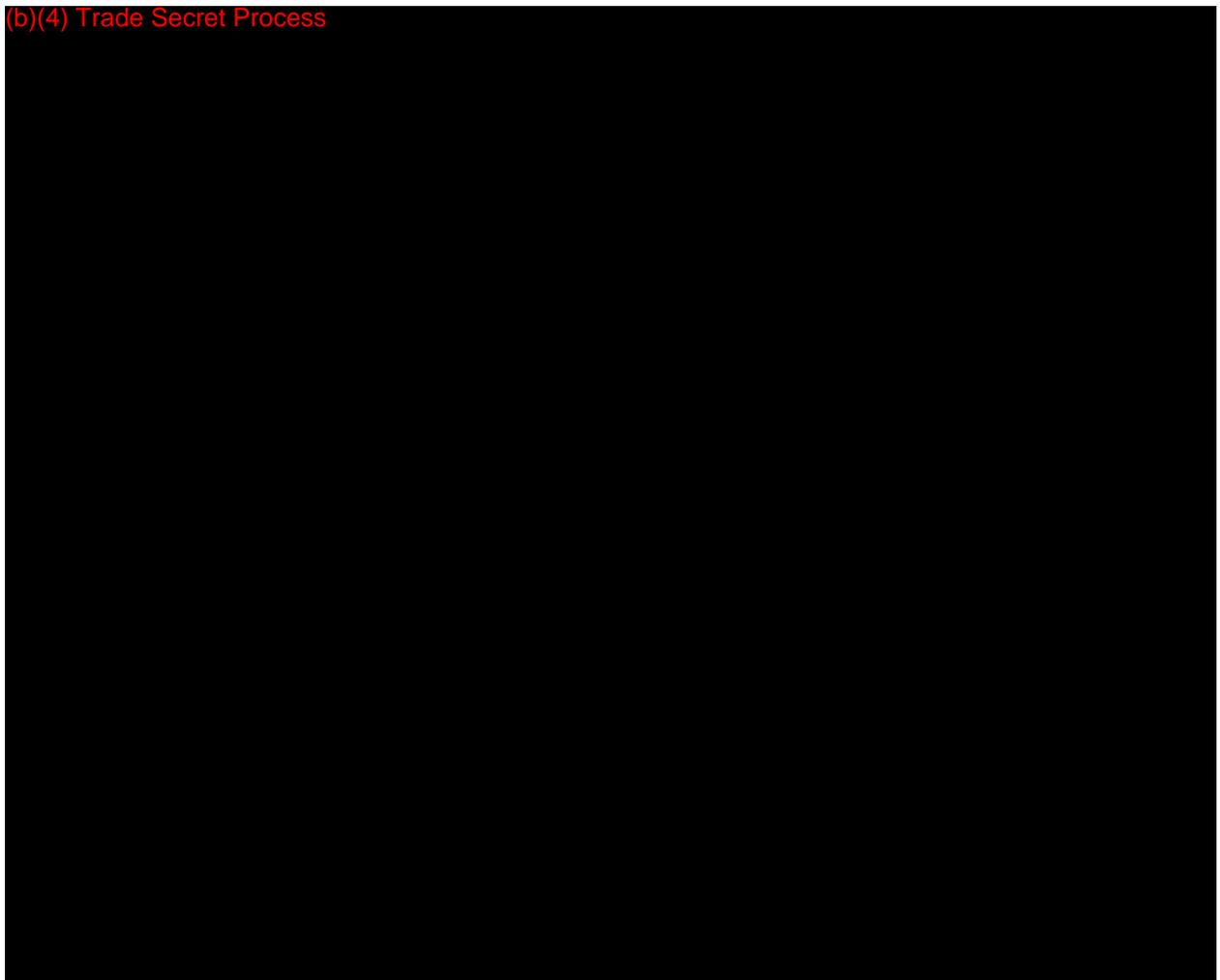
iHealth cloud

2 Intended use

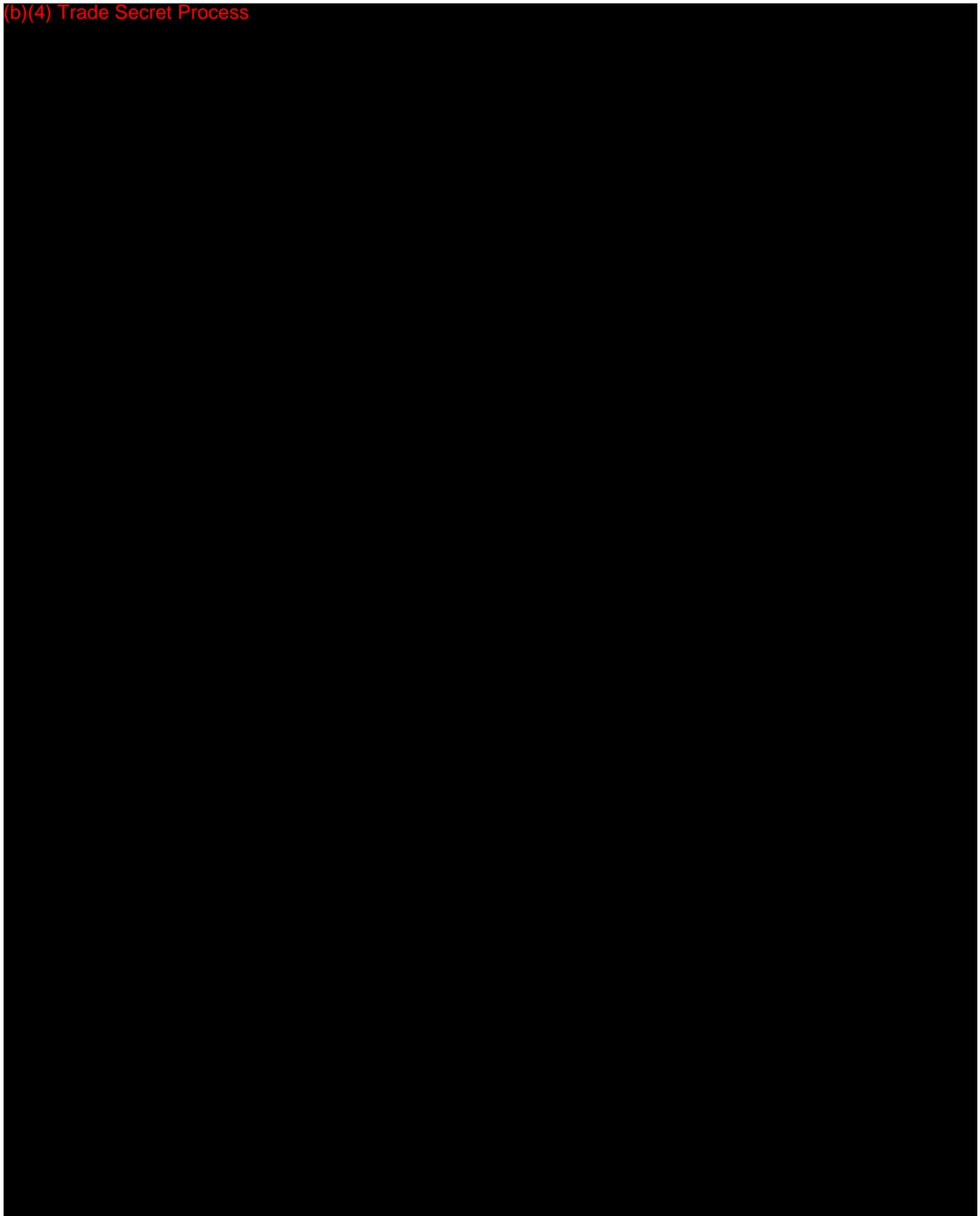
iHealth cloud's intended use is to retrospectively display and analyze related medical data. The Web Application is not intended for emergency use or real-time monitoring.

3 Performance specification

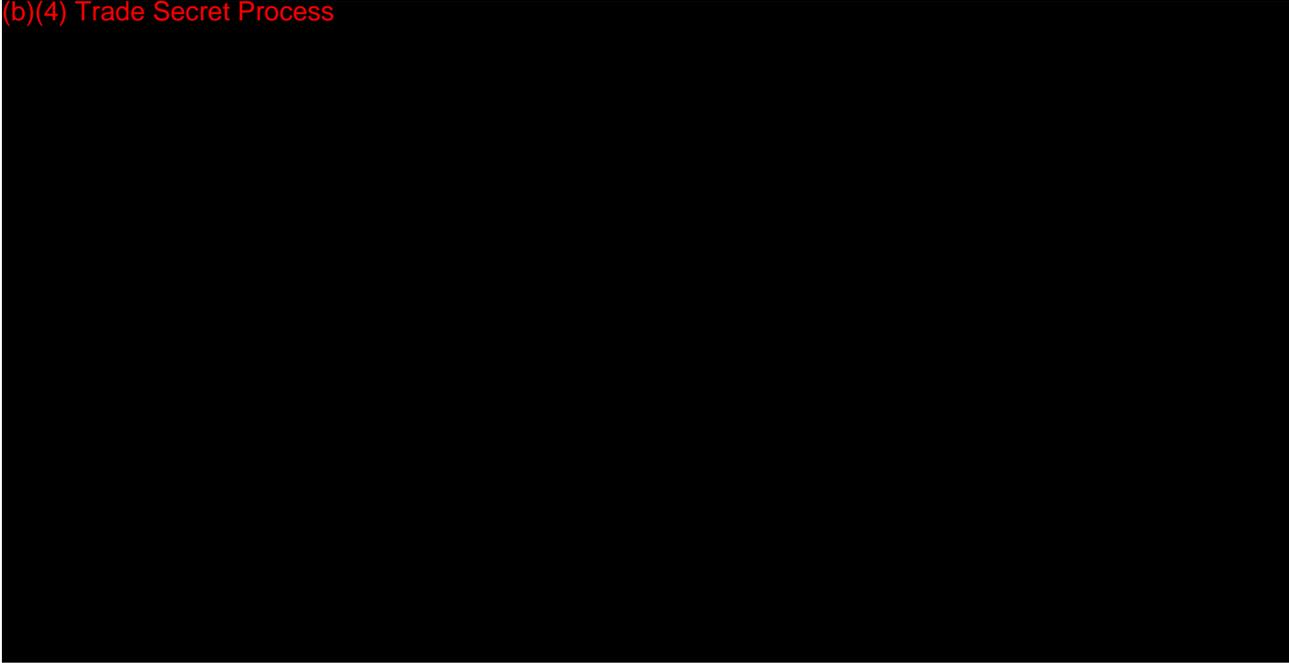
(b)(4) Trade Secret Process



(b)(4) Trade Secret Process

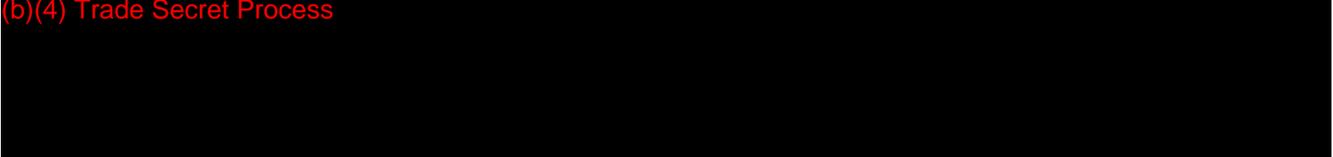


(b)(4) Trade Secret Process



iHealth Cloud FDA 510(k) Files

(b)(4) Trade Secret Process



This section does not apply.

This section does not apply.

Software Validation of iHealthCloud

This section doesn't apply.

This section does not apply

This section does not apply

Instructions for Completion of Form FDA 3674

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/ submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date** - This is the date of the application/submission which the certification accompanies.
3. & 4. - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/ cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/ submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.
9. **Certification** - This section contains three different check-off boxes.

Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/ submission which the certification accompanies.

Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.

Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/ submission.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. & 14. - Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number.

Form FDA 3674 (3/12) (BACK)

Mawii, Lal Pek *

From: Microsoft Outlook
To: celia4237@yahoo.com.cn
Sent: Monday, July 22, 2013 3:45 PM
Subject: Relayed: K131203 - Correspondence

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

celia4237@yahoo.com.cn (celia4237@yahoo.com.cn)

Subject: K131203 - Correspondence

Mawii, Lal Pek *

From: Microsoft Outlook
To: DCCLetters
Sent: Monday, July 22, 2013 3:45 PM
Subject: Delivered: K131203 - Correspondence

Your message has been delivered to the following recipients:

[DCCLetters \(DCCLetters@fda.hhs.gov\)](mailto:DCCLetters@fda.hhs.gov)

Subject: K131203 - Correspondence



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

COVER SHEET MEMORANDUM

From: Orlando Lopez

Subject: K131203

To: The Record

CTS decision code: SE

Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Please ensure the following is complete and accurate for a final clearance decision (i.e., SE, SE with Limitations, etc.):	Yes	No
Indications for Use Page Present (attach)	X	
510(k) Summary /510(k) Statement Present (attach)	X	
Truthful and Accurate Statement Present	X	
Is the device Class III? If yes, does firm include Class III Summary?		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		
Is this a combination product? (Please specify category, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)		N
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)		X
Is this device intended for pediatric use only?		X
Is this a prescription device? (If both prescription & OTC, check both boxes.)	X	X
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		
Is clinical data necessary to support the review of this 510(k)? For United States-based clinical studies only: Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)		
Does this device include an Animal Tissue Source?		
All Pediatric Patients age<=21		X
Neonate/Newborn (Birth to 28 days)		X
Infant (29 days -< 2 years old)		X
Child (2 years -< 12 years old)		X
Adolescent (12 years -< 18 years old)		X

Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age => 21 (different device design or testing, different protocol procedures, etc.)	X	
Transitional Adolescent B (18 - <= 21; No special considerations compared to adults => 21 years old)	X	
Nanotechnology		X
Mobile Application		X
MR Conditional		X
Device Contains Battery		
Companion Diagnostic		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) (Contact OC)		

Regulation Number
21 CFR 870.2770

Class (If unclassified, see 510(k) Staff)
Class II

Product Code
DXN

Additional Product Codes: , NBW, MNW

Digital Signature Concurrence Table	
Reviewer Sign-Off	Orlando Lopez-A 2013.07.16 19:07:31 -04'00'
Branch Chief Sign-Off	Linda J. Ricci 2013.07.18 14:32:12 -04'00'
Division Sign-Off	Digitally signed by Owen P. Faris Sr. Date: 2013.07.19 16:14:24 -04'00'

Table of content of
response to RTA of K131203

This is a replacement copy of the K131203 RTA response sent to DMC on May 20th, 2013.

I have reorganized the reply to the questions, so that it can be reviewed better, however, all the content is exactly the same as before.

Item	Content	Pages
001	Table of content of response to RTA of K131203	1
002	Response to RTA of K131203	4
003	Attachment 1. 510(K) Summary	2
004	Attachment 2. SE comparison	7
005	Attachment 3. Software Validation	68

510(k) Summary

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

1.0 submitter's information

Name: Andon Health Co., Ltd.
 Address: No 3, Jinping Road, Ya' an street TIANJIN,300193
 Phone number: 86-22-60526161
 Fax number: 86-22-6052 6162
 Contact: Yi Liu
 Date of Application: 4/24/2013

2.0 Device information

Trade name: iHealth cloud
 Common name: Patient Vital Signs Monitor Viewing Station
 Classification name: Patient Vital Signs Monitor Viewing Station

3.0 Classification

Production code: DXN, NBW, MNW
 Regulation number: 21 CFR 870.2770, 21 CFR 862.1345, 21 CFR 870.1130
 Classification: II
 Panel: 870 Cardiovascular, 862 Clinical Chemistry

4.0 Predict device information

1	Manufacturer: Andon health co., LTD Device: Apps-Health01 510(k) number: k122098
2	Manufacturer: Andon Medical Co., Ltd. Device: BG5/BG5L WIRELESS SMART GLUCOSE MONITORING SYSTEM 510(k) number: K123935

5.0 Device description

iHealth cloud is a cloud based, web software system. It is accessed from commercially available PC systems with a web browser and minimum performance specifications consistent with typical PC

hardware and equipment specifications. IHealth cloud accepts data both electronically as well as from manually input.

IHealth cloud is a medical device data system that displays and analyzes data received from iHealth home monitoring devices as well as manually input data. iHealth home monitoring devices include the apps and the device, such as KD-931, KD-936, KD-972 and Scale HS3 and HS5, AG-631, AG-632, AM3, PO3 and iHealth MyVitals.

6.0 Intended use

IHealth cloud's intended use is to retrospectively display and analyze related medical data. The Web Application is not intended for emergency use or real-time monitoring.

7.0 Performance summary

The software validation results demonstrated that the Clinical Application was in compliance with the guidelines and standards referenced in the FDA reviewer's guides and that it performed within its specifications and functional requirements for software.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of FDA regarding Medical device software.

3. Final conclusion

According to the above illustration, in the same intended use, iHealth Cloud is as same safe and effective as the predicated device.

iHealth Cloud FDA 510(k) Files

Software Validation of iHealth Cloud

