



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 9, 2016

Dictum Health, Inc.
% Daniel Kamm
Submission Correspondent
Kamm & Associates
8870 Ravello Ct
Naples, Florida 34114

Re: K152645
Trade/Device Name: IDM100
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: January 5, 2016
Received: January 8, 2016

Dear Daniel Kamm:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education 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 Industry and Consumer Education 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a large, light gray watermark of the FDA logo.

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known)

K152645

Device Name

IDM100

Indications for Use (Describe)

The IDM100 for use by clinicians and patients to collect, store, and transmit general patient health information and patient vital signs data between the patient and a health care professional. The IDM100 is intended for use on neonate (up to 28 days), pediatric (29 days to 12 years), adolescent (>12 years & <18 years) and adult (18 years and older) populations, in the clinical setting, or a remote location such as home or clinic with the clinician interacting with the patient and/or caregiver using secured video conferencing. The product is not intended for continuous patient monitoring.

Vital Sign and Cardiopulmonary Tests:

- Signal acquisition and display for 12 lead ECG waveform and 3 lead rhythm: for evaluation and diagnosis of patient cardiac function.
- Non-invasive blood pressure (NIBP): automatically measures systolic and diastolic pressure and pulse rate, as well as calculates an approximate mean arterial pressure (MAP).
- Patient temperature: provides temperature measurements from the tympanic membrane (ear) and manual entry of oral, rectal and axillary temperatures.
- SpO2 Oximeter: for the non-invasive measurement of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate.
- Electronic Stethoscope: for acquiring and monitoring of auscultation signals from the attached chest piece.
- Manual interface for height, weight, respiratory rate, and other manually captured patient information.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary As described in 21CFR807.92 for K152645

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Date prepared: January 30, 2016

Prepared by: Paul Landesman

1. Identification of the Device:

Proprietary – Trade Name: IDM100

Common Name: Integrated Medical Tablet

Classification Names/Product code	Regulation
Primary: Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms) Product Code MWI Other applicable product codes: DPS , DRX, DXN, DXQ, FLL, DQA, DQD.	870.2300

2. Substantially equivalent legally marketed device:

Manufacturer	Name of the Predicate Device	FDA 510(k) #	Regulation/Product Code
Remote Diagnostics Technologies LTD	Tempus IC2	K152124	21 CFR 870.2300/MWI

3. Indications for Use (intended use): The IDM100 for use by clinicians and patients to collect, store, and transmit general patient health information and patient vital signs data between the patient and a health care professional. The IDM100 is intended for use on neonate (up to 28 days), pediatric (29 days to 12 years), adolescent (>12 years & <18 years) and adult (18 years and older) populations, in the clinical setting, or a remote location such as home or clinic with the clinician interacting with the patient and/or caregiver using secured video conferencing. The product is not intended for continuous patient monitoring. Vital Sign and Cardiopulmonary Tests:

Signal acquisition and display for 12 lead ECG waveform and 3 lead rhythm: for evaluation and diagnosis of patient cardiac function.

Non-invasive blood pressure (NIBP): automatically measures systolic and diastolic pressure and pulse rate, as well as calculates an approximate mean arterial pressure (MAP). Patient temperature: provides temperature measurements from the tympanic membrane (ear) and manual entry of oral, rectal and axillary temperatures.

SpO2 Oximeter: for the non-invasive measurement of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate.

Electronic Stethoscope: for acquiring and monitoring of auscultation signals from the attached chest piece.

Manual interface for height, weight, respiratory rate, and other manually captured patient information.

4. Description of the device: The IDM100 is an integrated medical tablet with diagnostic equipment and secure HIPAA-compliant video conferencing capability facilitating Virtual Exam Rooms (VER) between patients and care providers anywhere. It captures patient vital signs and cardiopulmonary information with clinical accuracy. The IDM100 syncs the data seamlessly with electronic medical records (EMR) providing real-time access for all stakeholders in the continuum of care. The IDM100 transmits the patient data over a secure internet connection.

SYSTEM FEATURES

- Easy-to-use, 10.1 in/25.7 cm, high-resolution capacitive touch screen
- Lightweight, portable. Less than 4 pounds with battery.
- Secure audio/video conferencing and image capture while streaming data
- Expanded support for point-of care devices with 3 USB ports and Bluetooth
- Connects through WiFi, LAN,
- Oracle™ DMS Mobile Sync provides secure, fast data transfer
- Over 4.5 hours battery usage

Diagnose, monitor, and consult with even the most at-risk patients from virtually anywhere.

DIAGNOSTIC TOOLS

- 3 & 12-lead diagnostic resting ECG
- NIBP with MAP and heart rate (SunTech Advantage Mini module)
- Covidien Genius 2™ Tympanic Temperature
- NellCor Oximax™ SpO2 with respiratory and pulse rate
- Electronic stethoscope with CD-quality audio
- 2 internal HD cameras for images and video conferencing

The diagnostic tools other than ECG are implemented via modules and accessories which have all had previous FDA clearances:

Device Product Code and Name:	Regulation	Clearance
DRX: Electrode, Electrocardiograph (now exempt)	870.2360	K000690
DXN: Noninvasive blood pressure (NIBP)	870.1130	K151071
DXQ: Blood Pressure Cuff	870.1120	K112544
FLL: Patient (Tympanic) temperature	880.2910	K060649
DQA: Oximeter, SpO2, pulse rate, respiration rate	870.2700	K123581
DQD: Electronic Stethoscope	870.1875	K081032

5. Comparison with predicate devices – IFU and Technological characteristics

	Tempus IC2 K152124	New Device: Dictum Health Inc., IDM100 K152645
Indications for Use	<p>“The Tempus IC2 is intended to aid with the diagnosis of a person presenting as unwell or sick when they are in a location remote from immediate medical assistance. The device allows the User to take vital signs data from a patient and to transmit that data to medical professionals located at the response centre elsewhere. Typical examples are remote land, sea or air locations. The Tempus IC2 is intended primarily to be used by medically unqualified people who have received basic training in the use of the device. Medical expertise is provided through communication with the Response Centre which would be staffed by physicians who</p>	<p>The IDM100 for use by clinicians and patients to collect, store, and transmit general patient health information and patient vital signs data between the patient and a health care professional. The IDM100 is intended for use on neonate (up to 28 days), pediatric (29 days to 12 years), adolescent (>12 years & <18 years) and adult (18 years and older) populations, in the clinical setting, or a remote location such as home or clinic with the clinician interacting with the patient and/or caregiver using secured video conferencing. The product is not intended for continuous patient monitoring.</p> <p>Vital Sign and Cardiopulmonary Tests:</p>

	Tempus IC2 K152124	New Device: Dictum Health Inc., IDM100 K152645
	would advise the operator on the nature of the medical incident. The Tempus IC2 is intended to be used where a physician or other medically trained staff may or may not be present but where remote physician support is required. Tempus IC2 measures non-invasive blood pressure, SpO2, pulse rate, respiration rate and ETCO2, 12 Lead ECG, tympanic temperature (via a wireless external module) and blood glucose (via a wireless external module). The Tempus IC2 is suitable for use on adults or children (over 10 years old and over 20kg in weight).”	Signal acquisition and display for 12 lead ECG waveform and 3 lead rhythm: for evaluation and diagnosis of patient cardiac function. Non-invasive blood pressure (NIBP): automatically measures systolic and diastolic pressure and pulse rate, as well as calculates an approximate mean arterial pressure (MAP). Patient temperature: provides temperature measurements from the tympanic membrane (ear) and manual entry of oral, rectal and axillary temperatures. SpO2 Oximeter: for the non-invasive measurement of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. Electronic Stethoscope: for acquiring and monitoring of auscultation signals from the attached chest piece. Manual interface for height, weight, respiratory rate, and other manually captured patient information.
Indications are functionally the same except for ETCO2, and blood glucose which we chose not to support at this time. Predicate does not include stethoscope.		
External Communication	Ethernet, Wi-Fi, Cellular	Ethernet and Wi-Fi. These two modes are sufficiently ubiquitous to be functionally equivalent to the predicate.
User Interface	LCD Color Touch Screen	800 x 600 10.1 in Capacitive Touch, full color.
Photo		
Environment to be used in	Hospital, Clinic, Home	Hospital, Clinic, Home
Dimensions	H 203 mm 7.99" x W 289 mm 2.91" x D 74 mm 2.91 "	H: 1.5 in/2.6 cm x W: 8 in/21 cm x L: 10 in/26 cm (Designed for portability, more flexible)

	Tempus IC2 K152124	New Device: Dictum Health Inc., IDM100 K152645
Weight, incl. battery	2.8 kg 6.17 lb.	3.8 lbs (Lighter)
Patient cable and leads	Meets or exceeds ANSI/AAMI EC53, EN/IEC 60601-2-25 and EN/IEC 60601-2-51	Meets or exceeds ANSI/AAMI EC53, EN/IEC 60601-2-25 and EN/IEC 60601-2-51 (Same)
Protection against electric shock	Class I, internally powered Type CF	Class I, internally powered Type CF (Same)
Prescription or OTC	Prescription	Prescription (Same)
Additional modes	Not applicable	Electronic stethoscope 2 internal HD cameras for medical images and video Video conferencing (More flexible)
Power	Rechargeable Battery, 6 hour	Rechargeable Battery, 4.5 hour (Adequate for use, warning message when power reserve is at 20% or lower)
Battery Recharge	From AC Line, 6 hours.	From AC Line, < 3 hours. (Faster recharge)

6. **Safety and Effectiveness:** The IDM100 labeling contains instructions for use and necessary cautions, warnings and notes to provide for safe and effective use of the device. Risk Management is ensured via the company's design control and risk management procedures. Potential hazards are controlled via development and verification and validation testing. The comparison table above shows substantial equivalence. Additional modes are provided via FDA cleared medical devices.
7. **Testing Information and Performance:** The following testing has been successfully performed and documented:
- Software Validation and Risk Assessment per FDA guidelines for the Moderate Level of Concern.
 - Transportation Simulation Evaluation Testing: One packaged IDM100 Integrated Medical Tablet was sent to DDL for transportation simulation evaluation per the following standards listed in the table below. Results were satisfactory.
 - Simulated Low Perfusion Saturation And Pulse Rate Accuracy Study Using A Pulse Simulator. Results were satisfactory.
 - Tympanic Thermometer standard Compliance: Accuracy testing. Results were satisfactory.
 - NIBP Device Evaluation Testing: Visual inspections and testing to EN1060-3, Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems; Results were satisfactory.
 - Design validation (usability study) for the IMD100 indications for use in clinical and non-clinical settings.
 - Standards testing protocols per the following list of standards:

Standards No.	Standards Title	Version
IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	2005 + CORR. 1 (2006) + CORR. 2 (2007)
IEC 60601-1-2 ed3.0 (2007-03),	General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	ed3.0 (2007-03)
IEC 60601-2-25 ed 2.0 (2011-10),	Particular requirements for the basic safety and essential performance of electrocardiographs	ed 2.0 (2011-10),
IEC 60601-2-49 ed 2.0	Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment	ed 2.0
IEC 60601-1-11	General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	1 st ed
ISTA Procedure 2A (2011) ASTM D4169-14	Partial Simulation Performance Test Procedure, Packaged-Products 150 lb (68 kg) or Less Standard Practice for Performance Testing of Shipping Containers and Systems	2011

8. Clinical Testing: Although not required for a determination of substantial equivalence, clinical evaluation was performed to demonstrate performance equivalence to the predicate for the ECG function. The testing can be summarized this way: We compared 18 normal and abnormal ECG patients to the predicate ECG device. The IDM100 and the Welch Allyn CP150 (predicate) provide comparable testing result, with no impact to the interpretation of the patients ECG. There was no day-to-day or unit-to-unit variation observed in the IDM100 testing. There is no direct comparison between the 12-lead and 3-lead test. The 12-lead ECG test results are comparable between the IDM100 and the CP150 (Predicate Device). SUMMARY CONCLUSION: Testing showed a direct correlation between the IDM100 and Welch Allyn CP150, achieving Substantial Equivalence. The Predicated Device does not have an indication for use for 3-lead ECG testing. The IDM100 3-lead ECG test could not be evaluated against the Predicate Device. Passing IEC 60601-02-25 confirms the safety and accuracy for IDM100 12-lead and 3-lead IDM ECG testing.
9. Conclusion: The IDM100 has the same intended use as the predicate device. Test results demonstrate that the device is safe, effective, and does not raise any new potential safety risks. In all material respects, the IDM100 is substantially equivalent to the predicate device.