DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 14, 2017

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

Re: K170798
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, DPS, DRX, DXN, DXQ, FLL, DQA, DQD, BZG, EWO
Dated: June 16, 2017
Received: June 16, 2017

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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170798

Device Name
IDM100

Indications for Use *(Describe)*
The IDM100 is 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, except as noted below), adolescent (between 13 years and 17 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 via secured video conferencing. The IDM100 is not intended for continuous 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. ECG calculation of diagnostic measurements is provided for adult patients only.

• Non-invasive blood pressure (NIBP) automatically measures systolic and diastolic pressure and pulse rate, while calculating mean arterial pressure (MAP). The equation used to calculate MAP provides an approximate value.

• 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), pulse rate, and optional Respiratory Rate.

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

• Spirometry captures, displays, stores, and compares pulmonary function measures and waveforms. The spirometer should only be used with patients able to understand and perform the testing instructions. Indicated for use on pediatric, adolescent, and adult patients only. Patients must be six years of age or older. Administration of the spirometry test must be performed by a health care professional (HCP) who is physically with the test subject. Spirometry tests are not to be administered by a patient.

• Screening hearing test using pure tone method. Indicated for pediatric, adolescent and adult only. Patients must be six years of age or older. The administration of the hearing test must be performed by a health care professional (HCP) who is physically with the test subject. . Audiometry tests (hearing tests) are not to be administered by a patient.

• 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; K171098
Dictum Health Inc.
255 3rd Street, Suite 102
Oakland, CA 94607
(510) 295-4450 Fax: (510) 246-3293
www.dictumhealth.com
Date prepared: July 10, 2017
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. This submission ADDS: ECG Measurement (DPS), Spirometry (BZG), and Audiometry (EWO)	870.2300

2. Substantially equivalent legally marketed device:

Manufacturer	Name of the Predicate Device	FDA 510(k) #	Regulation/Product Code
Dictum Health Inc.	IDM100	K152645	21 CFR 870.2300/MWI

3. **Indications for** Use **(intended use):** The IDM100 is 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, except as noted below), adolescent (between 13 years and 17 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 via secured video conferencing. The IDM100 is not intended for continuous 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. ECG calculation of diagnostic measurements is provided for adult patients only.
   - Non-invasive blood pressure (NIBP) automatically measures systolic and diastolic pressure and pulse rate, while calculating mean arterial pressure (MAP). The equation used to calculate MAP provides an approximate value.
   - 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), pulse rate, and optional Respiratory Rate.
   - Electronic Stethoscope for acquiring and monitoring of auscultation signals from the attached chest piece.
   - Spirometry captures, displays, stores, and compares pulmonary function measures and waveforms. The spirometer should only be used with patients able to understand and perform the testing instructions. Indicated for use on pediatric, adolescent, and adult patients only. Patients must be six years of age or older. Administration of the spirometry test must be performed by a health care professional (HCP)who is physically with the test subject. Spirometry tests are not to be administered by a patient.
   - Screening hearing test using pure tone method. Indicated for pediatric, adolescent and adult only. Patients must be six years of age or older. The administration of the hearing test must be

performed by a health care professional (HCP) who is physically with the test subject. Audiometry tests (hearing tests) are not to be administered by a patient

- 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 transmist the the patient data over a secure internet connection. The IDM100 applications range from routine screening in ambulatory care facilities, to physician offices, hospitals and patient homes with traveling HCP (Health Care Professional) or by the patient (layperson). (See indication of use for limitations.) The diagnostic capabilities are designed for the clinical populations described in the indications, including neonatal, pediatric, and adult.

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 with waveform measurements
• 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
• Spirometer. Spirometry tests are not to be administered by a patient.
• Audiometer. Audiometry tests (hearing tests) are not to be administered by a patient
• 2 internal HD cameras for images and video conferencing

The diagnostic tools other than ECG and Spirometry 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	K051904
FLL: Patient (Tympanic) temperature	880.2910	K060649
DQA: Oximeter, SpO2, pulse rate, respiration rate	870.2700	K123581
DQD: Electronic Stethoscope	870.1875	K081032
DPS: ECG Measurement	870.2340	K062282
BZG: Spirometry	868.1840	(This submission)
EWO: Audiometery (now exempt)	874.1050	N/A

5. Comparison with predicate devices – IFU and Technological characteristics.

	Dictum Health Inc., IDM100 K152645	New Device: Dictum Health Inc., IDM100
Indications for 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.	The IDM100 is 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, except as noted below), adolescent (between 13 years and 17 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 via secured video conferencing. The IDM100 is not intended for continuous 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. ECG calculation of diagnostic measurements is provided for adult patients only. • Non-invasive blood pressure (NIBP) automatically measures systolic and diastolic pressure and pulse rate, while calculating mean arterial pressure (MAP). The equation used to calculate MAP provides an approximate value. • 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), pulse rate, and optional Respiratory Rate. • Electronic Stethoscope for acquiring and monitoring of auscultation signals from the attached chest piece. • Spirometry captures, displays, stores, and compares pulmonary function measures and waveforms. The spirometer should only be used with patients able to understand and perform the testing instructions. Indicated for use on pediatric, adolescent, and adult patients only. Patients must be six years of age or older. Administration of the spirometry test must be performed by a health care professional (HCP) who is

	Dictum Health Inc., IDM100 K152645	New Device: Dictum Health Inc., IDM100
		physically with the test subject. Spirometry tests <u>are not</u> to be administered by a patient. • Screening hearing test using pure tone method. Indicated for pediatric, adolescent and adult only. Patients must be six years of age or older. The administration of the hearing test must be performed by a health care professional (HCP)who is physically with the test subject. Audiometry tests (hearing tests) <u>are not</u> to be administered by a patient. • Manual interface for height, weight, respiratory rate, and other manually captured patient information.
Indications are functionally the same except for added functionality: ECG Measurement, Spirometry, and Audiometry		
External Communication	Ethernet and Wi-Fi. These two modes are sufficiently ubiquitous to be functionally equivalent to the predicate.	Ethernet and Wi-Fi. These two modes are sufficiently ubiquitous to be functionally equivalent to the predicate.
User Interface	800 x 600 10.1 in Capacitive Touch, full color.	800 x 600 10.1 in Capacitive Touch, full color.
Photo		
Environment to be used in	Hospital, Clinic, Home	Hospital, Clinic, Home
Dimensions	H: 1.5 in/2.6 cm × W: 8 in/21 cm × L: 10 in/26 cm (Designed for portability, more flexible)	H: 1.5 in/2.6 cm × W: 8 in/21 cm × L: 10 in/26 cm (Designed for portability, more flexible)
Weight, incl. battery	3.8 lbs	3.8 lbs (SAME)
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)

	Dictum Health Inc., IDM100 K152645	New Device: Dictum Health Inc., IDM100
Prescription or OTC	Prescription	Prescription (Same)
Additional modes	Not applicable	ECG QRS Measurement, Spirometry, Audiometry
Power	Rechargeable Battery, 4.5 hour (Adequate for use, warning message when power reserve is at 20% or lower)	SAME
Battery Recharge	From AC Line, < 3 hours.	SAME
Spirometry Substantial Equivalence		
	Spirobank G, K072979 MIR Medical International Research	New Device: Dictum Health Inc., IDM100
Indications	The Spirobank G spirometer is intended to be used by a physician or by a patient under the instruction of a physician or paramedic. The device is intended to test lung function and can make spirometry testing in people of all ages, excluding infiants and neonates. It can be used in any setting.	Spirometry for lung capacity evaluation (FVC). Indicated for use on pediatric, adolescent, and adult patients only. Patients must be six years of age or above and capable of performing the test. (This is equivalent to the predicate since infants and neonates cannot cooperate with the testing.)
Functions	Graphic display, USB, Bluetooth	SAME
Testing	Spirometry testing was performed according with American Thoracic Society (ATS) Standards. The results obtained were within the range of accuracy required by ATS.	SAME
Safety	IEC 60601-1 Standard, this product and its component parts are of type BF. EMC per IEC 60601-1-2	SAME
Operating Environment	Designed for use in a doctor's office, in a hospital or directly by the patient during day-to-day activities for the monitoring of physical conditions. Can be used in any environment.	SAME
Sensor	Reusable or disposable	Single patient use disposable only
Power	Battery (disposable)	Battery (rechargeable)
Fundamental underlying technology	Bi-directional digital turbine using Infrared interruption.	Honeywell pressure sensor in the range of the Geratherm flow transducer measures the differential pressure and converts it to digitized data.
Flow range	± 16 L/s	± 14 L/s Meets ATS guideline
Tests	FVC Forced Vital Capacity (L)	SAME
	FEV1 Volume expired in the 1st second of the test (L)	SAME
	FEV1/FVC FEV1/FVC x 100 %	SAME

	Dictum Health Inc., IDM100 K152645	New Device: Dictum Health Inc., IDM100
	PEF Peak expiratory flow L/s	SAME
	FET Forced expiratory time s	SAME
	FIVC Forced inspiratory volume (L)	SAME
	PIF Peak inspiratory flow L/s	SAME

6. Safety and Effectiveness: The IDM labeling contains instructions for use and necessary cautions, warnings and notes to allow for use of the device as intended. 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 (or exempt) medical devices. Clearance numbers for provided accessories are provide in the description section (4) above.

7. Testing Information and Performance: The following testing has been successfully performed and documented:
   a. Software Validation and Risk Assessment per FDA guidelines for the Moderate Level of Concern.
   b. 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.
   c. Simulated Low Perfusion Saturation And Pulse Rate Accuracy Study Using A Pulse Simulator. Results were satisfactory.
   d. Tympanic Thermometer standard Compliance: Accuracy testing. Results were satisfactory.
   e. 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.
   f. Design validation (usability study) for the IMD100 indications for use in clinical and non-clinical settings. Results were satisfactory.
   g. Additional mode validation: Audiometery. Tested to ANSI/ASA S3.6-2010: Specification for Audiometers. Results were satisfactory.
   h. Additional mode validation: ECG Measurements were validated with three methods: CSE Database Verification, Data Collection, and a Clinical Verification.
   i. Additional mode validation: Spirometry, evaluated according to ATS/ERS Task Force Standardisation of Lung Function Testing: Standardisation of spirometry (2005). Results were satisfactory. Biocompatibility test reports were obtained and reviewed (cytotoxicity, irritation, and sensitization) for the patient contact sensor and were satisfactory. Human factors usability testing was also successfully conducted.
   j. Standards testing protocols per the following list of standards: (Results were satisfactory.)

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	1st 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: Not applicable.

9. Conclusion: The IDM100 has the same intended use as the predicate device except for the added modes, which we have validated. Test results demonstrate that the device is as safe and effective as the predicate device (K152645). In all material respects, the IDM100 is substantially equivalent to the predicate device.