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5 510(K) Summary

510 (K) Summary				
5.1	**Submitter/Owner**	**Oricare, Inc.** FDA #3009129579 1900 AM Drive Quakertown, Pennsylvania 18951 +1-215-538-2470 Phone		
5.2	**Key Contacts**	**Kurtis Montegna** Quality Assurance & Regulatory Affairs Manager kmontegna@Oricaremed.com **David Jamison** Executive VP djamison@Oricaremed.com		
5.3	**Date Prepared**	06/13/2013		
5.4	**510(K) Submission Type**	This is a traditional 510(K)		
5.5	**Prior Submissions**	There have been no prior submissions to FDA about this device.		
5.6	**Trade Name**	A9800 Anesthesia Workstation		
5.7	**Common Name**	Anesthesia Workstation		
5.8	**Classification Name**	Class II BSZ Panel 73: Anesthesiology Subpart F: Therapeutic Devices CFR 868.5160 Gas machine for anesthesia or analgesia		
5.9	**Predicate Devices**	K123125	GE Datex-Ohmeda Avance	BSZ
		K123211	Mindray A5 Anesthesia Delivery System	BSZ
		K042607	Draeger Apollo US	BSZ
The A9800 Anesthesia Workstation is substantially equivalent to the legally marketed (predicate) GE-Datex-Ohmeda Avance K123125, the Mindray A5 K123211, and the Draeger Appollo K042607.				

5.10 A9800 – Description of the device per 21 CFR 807.92(a) (4)

The A9800 Anesthesia Workstation provides accurate, pneumatically driven and electronically controlled ventilation. The A9800 includes modes that provide patient-appropriate defaults and ranges. The A9800 was rigorously tested to harmonized standards, which included a full human factors study with physicians.

Like the predicate device (K123125) A9800 provides complete anesthesia ventilation capabilities that include traditional and "intensive care type" ventilation modes. Low-flow anesthesia delivery creates savings by lower facility gas usage. The integrated electronic flow meter provides accurate monitoring and intuitive operation. The A9800 bellows contains breathing gasses to be delivered to the patient as does the predicate device. Likewise, for patient safety both the predicate and the A9800 maintain positive pressure in the breathing system so any leakage that occurs is outward. PEEP (Positive End Expiratory Pressure) in A9800 is electronically regulated for patient safety and is substantially equivalent to the predicate device. Both the A9800 and the predicate device offer an ACGO (alternate common gas outlet) to provide fresh gas to non-rebreathing adapters.

The A9800 and the predicate device (K123125) include the following ventilation modes: Volume Mode, Pressure Control Mode, Pressure Support Mode with Apnea Backup, Synchronized Intermittent Mandatory Ventilation Mode (SIMV), and Pressure Controlled Ventilation with Volume Guarantee (PCV-VG). The predicate offers SIMV-PCV-VG, which is not offered on the A9800. The A9800 method of control, of the maximum applied breathing pressure, during manual ventilation (by using a single turn APL valve along with a manual breathing bag) is equivalent to the predicate device.

Both the predicate device (K123125) and the A9800 have an accessory gas analyzer that can monitor FiO_2 and patient respiratory gas for CO_2, N_2O, and five types of anesthetic agents. A9800 and the predicate also have an Anesthetic Gas Scavenging System (AGSS) for the safe and effective removal of waste gas.

Both the predicate device (K123125) and the A9800 utilize a large 15 inch touch screen monitor with a navigator wheel that provides a simple intuitive interface for user control. The screen can be tilted upward and downward according to the doctor's needs and position. The parameter areas on the main screen are shown in different colors for ease of identification. The waveforms and alarm records are clearly shown for easy review by the clinician.

Like the predicate device (K123125) the A9800 displays patient data with waveforms and spirometry loops. A reference loop can be stored to best understand changes in patient response to therapy. Both the A9800 and its predicate device (K123125) contain electronic flow meters for O_2, Air, and N_2O, which are designed especially for low flow applications. Electronic fresh gas flow displays are used in addition to traditional mechanical flow controllers for enhanced patient safety. Data communications export is supported to connect to the Hospital IT systems and support electronic medical records (EMR).

5.11 Intended Use as required by 807.92(a)(5)

Item of comparison	GE Avance Predicate	Mindray A5 Predicate	Draeger Apollo Predicate	Oricare A9800 Current Submission	Substantial Equivalence
Intended use	The GE-Datex Avance CS² Anesthesia System is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (neonatal, pediatric, adult). The device is intended for volume or pressure control ventilation.	The A5/A3 Anesthesia System is a device used to administer to a patient, continuously or intermittently, a general inhalation anesthetic, and to maintain a patient's ventilation. The A5/A3 is intended for use by licensed clinicians, for patients requiring anesthesia within a health care facility, and can be used for adult and pediatric populations.	The Apollo is indicated as a continuous flow anesthesia system. The Apollo may be used for manually assisted or automatic ventilation, delivery of gases and anesthetic vapor, and monitoring of oxygen and CO2 concentration, breathing pressure, respiratory volume, and anesthetic agent concentration and identification.	The A9800 Anesthesia Workstation provides general inhalation anesthesia and ventilatory support for adolescents to adults in an operating room environment. The device is indicated for volume or pressure control ventilation.	**No Difference SE**
Indications for Use	The GE-Datex Avance CS² Anesthesia System is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (neonatal, pediatric, adult). The device is intended for volume or pressure control ventilation.	The A5/A3 Anesthesia System is a device used to administer to a patient, continuously or intermittently, a general inhalation anesthetic, and to maintain a patient's ventilation. The A5/A3 is intended for use by licensed clinicians, for patients requiring anesthesia within a health care facility, and can be used for adult and pediatric populations.	The Apollo is indicated as a continuous flow anesthesia system. The Apollo may be used for manually assisted or automatic ventilation, delivery of gases and anesthetic vapor, and monitoring of oxygen and CO2 concentration, breathing pressure, respiratory volume, and anesthetic agent concentration and identification.	The A9800 Anesthesia Workstation provides general inhalation anesthesia and ventilatory support for adolescents to adults in an operating room environment. The device is indicated for volume or pressure control ventilation.	**No Difference SE**

5.12 Primary Predicate Device Comparison Table – Physical Specifications

Item of comparison	GE Avance Predicate	Mindray A5 Predicate	Draeger Apollo Predicate	Oricare A9800 Current Submission	Substantial Equivalence
Target Population	Neonatal, pediatric, adult	Pediatric, Adult	Neonatal, pediatric, adult	Adolescent to Adult	**No Difference - SE**
Anatomical Sites	No patient contacting parts	No patient contacting parts	No patient contacting parts	No patient contacting parts	**No Difference - SE**
Where Used	Hospital Environment	Hospital Environment	Hospital Environment	Hospital Environment	**No Difference - SE**
Power	AC Power/DC Backup	AC Power/DC Backup	AC Power/DC Backup	AC Power/DC Backup	**No Difference - SE**
Human Factors	Tested	Tested	Tested	Tested	**No Difference - SE**
Electrical Safety	ISO 60601-1	ISO 60601-1	ISO 60601-1	ISO 60601-1	**No Difference - SE**
Mechanical Safety	ISO 60601-1	ISO 60601-1	ISO 60601-1	ISO 60601-1	**No Difference - SE**
Chemical safety	NA	NA	NA	NA	**No Difference - SE**
Thermal Safety	NA	NA	NA	NA	**No Difference - SE**
Radiation Safety	NA	NA	NA	NA	**No Difference - SE**
Height	53 inches	55 inches	59 inches	56 inches	**Substantially Equivalent**
Width	28 inches	41 inches	33 inches	36 inches	**Substantially Equivalent**
Depth	29 inches	31 inches	31 inches	30 inches	**Substantially Equivalent**

5.12 **Primary Predicate Device Comparison Table – Physical Specifications (Continued)**					
Item of comparison	**GE Avance** Predicate	**Mindray A5** Predicate	**Draeger Apollo** Predicate	**Oricare A9800** Current Submission	**Substantial Equivalence**
Weight	275 pounds	330 pounds	363 pounds	287 pounds	**Substantially Equivalent**
Operating Temp	50-100 °F	50-104 °F	59-104 °F	50-104 °F	**Substantially Equivalent**
Operating Humidity	Less than 95% RH	15-90% Non-condensating	25-85% Non-condensating	15-90% Non-condensating	**Substantially Equivalent**
Top Shelf Width	26 inches	24 inches	24 inches	25.5 inches	**Substantially Equivalent**
Top Shelf Depth	15.75 inches	14 inches	20 inches	15 inches	**Substantially Equivalent**
Top shelf Weight Limit	75 pounds	88 pounds	100	55 pounds	**Substantially Equivalent**
Work Surface Height	32 inches	33 inches	Not Specified	33 inches	**Substantially Equivalent**
Work Surface	409 in^2	364 in^2	234 in^2	319 in^2	**Substantially Equivalent**
Din Rail	Yes	Yes	Yes	Yes	**Substantially Equivalent**
Drawers	2	2	3	3	**Substantially Equivalent**
Drawer Height	6.9 inches	5.3 inches	Not Specified	5.1 inches	**Substantially Equivalent**
Drawer Width	13 inches	17.3 inches	Not Specified	19.4 inches	**Substantially Equivalent**
Drawer Depth	10.4 inches	15.1 inches	Not Specified	13.8 inches	**Substantially Equivalent**
Total Storage (all drawers)	1866 in^3	2769 in^3	Not Specified	4096 in^3	**Substantially Equivalent**
Casters	4	4	4	4	**Substantially Equivalent**
Brakes	Central Brake for Casters	Central Brake for Casters	Central Brake for Casters	Locking front casters	**Substantially Equivalent**

5.13 Primary Predicate Device Comparison Table – Ventilator Operating Specifications

Item of comparison	GE Avance Predicate	Mindray A5 Predicate	Draeger Apollo Predicate	Oricare A9800 Current Submission	Substantial Equivalence
Volume Control with tidal compensation	Yes	Yes	Yes	Yes	**Substantially Equivalent**
Pressure Control	Yes	Yes	Yes	Yes	**Substantially Equivalent**
Pressure Control with Volume Guaranteed (PCV-VG)	Yes	Yes	NO	Yes	**Substantially Equivalent**
Synchronized Intermittent Mandatory Ventilation (SIMV-VCV, SIMV-PCV)	Yes	Yes	No	Yes	**Substantially Equivalent**
Synchronized Intermittent Mandatory Ventilation (SIMV-PCV-VG)	Yes	Yes	Not Offered	Not Offered	**There is no patient safety risk by not offering this mode - SE**
Pressure Support	Yes	Yes	Yes	Yes	**Substantially Equivalent**
Apnea Backup	Yes	No	Yes	Yes	**Substantially Equivalent**
Tidal Volume Range (V_T)	20 to 1500 mL	0 to 1500 mL	20 to 1400 mL	20 to 1500 mL	**Substantially Equivalent**
Incremental Settings (20-100 mL)	5 mL	1	Not Specified	5 mL	**Substantially Equivalent**
Incremental Settings (100-300)	10 mL	1	Not Specified	10 mL	**Substantially Equivalent**
Incremental Settings (300-1000)	25 mL	1	Not Specified	10 mL	**Predicate and A9800 offer Vt adjustment and for this setting the A9800 has better resolution -SE**
Incremental Settings (1000-1500)	50 mL	1	Not Specified	50 mL	**Substantially Equivalent**
Minute Volume Measurement Range	2 - 20 L/min	0 to 30 L/min	0 – 99.9 L/min	0 to 30 L/min	**Substantially Equivalent**
Pressure ($P_{inspired}$) range	5 – 60 cm H_2O	5-70 cm H_2O	5-70 cm H_2O	5 – 70 cm H_2O	**Both predicate and A9800 offer $I_{inspired}$ settings and the A9800 adjustment range is slightly greater - SE**

5.14 Predicate Device(s) Comparison Table – Breathing Circuit

Item of comparison	GE Avance Predicate	Mindray A5 Predicate	Draeger Apollo Predicate	Oricare A9800 Current Submission	Substantial Equivalence
N_2O shut off with loss of O_2 pressure?	Yes	Yes	Yes	Yes	Substantially Equivalent
O_2 flush range	>35 L/min	>35 L/min	>35 L/min	>35 L/min	Substantially Equivalent
Fresh gas flow range	0 mL/min – 15 L/min	0 mL/min – 15 L/min	0 and 0.2 – 18 L/min	0 mL/min – 15 L/min	Substantially Equivalent
O_2 flow accuracy	±5% or ±20 mL/min	± 10% or 120 mL /min	± 10% or 120 mL /min	± 10% or 120 mL /min	Substantially Equivalent
O_2 concentration range	21 – 100%	21 – 100%	21 – 100%	21 – 100%	Substantially Equivalent
Hypoxic Guard	Yes	Yes	Yes	Yes	Substantially Equivalent
Circle Mode	Yes	Yes	Yes	Yes	Substantially Equivalent
ACGO Mode	Yes	Yes	Yes	Yes	Substantially Equivalent
CO_2 Canister	Yes	Yes	Yes	Yes	Substantially Equivalent
Exhalation port	22 mm OD ISO 15 mm ID taper	22 mm OD ISO 15 mm ID taper	22 mm OD ISO 15 mm ID taper	22 mm OD ISO 15 mm ID taper	Substantially Equivalent

5.14 Predicate Device(s) Comparison Table – Breathing Circuit (Continued)					
Item of comparison	**GE Avance** Predicate	**Mindray A5** Predicate	**Draeger Apollo** Predicate	**Oricare A9800** Current Submission	**Substantial Equivalence**
Inhalation port	22 mm OD ISO 15 mm ID taper	22 mm OD ISO 15 mm ID taper	22 mm OD ISO 15 mm ID taper	22 mm OD ISO 15 mm ID taper	Substantially Equivalent
Bag port	22 mm OD	22 mm OD	22 mm OD	22 mm OD	Substantially Equivalent
Bag-to-Ventilator switch	Bi-Stable	Bi-Stable	Bi-Stable	Bi-Stable	Substantially Equivalent
Bag-to-Ventilator control	Controls ventilator and direction of breathing gas	Controls ventilator and direction of breathing gas	Controls ventilator and direction of breathing gas	Controls ventilator and direction of breathing gas	Substantially Equivalent
APL valve range	0.8 to 70 cm H_2O	0.8 to 70 cm H_2O	0.8 to 70 cm H_2O	0.8 to 70 cm H_2O	Substantially Equivalent
Compliance compensation mechanical modes	Auto compensate	Auto compensate	Auto compensate	Auto compensate	Substantially Equivalent
Gas Supply Pressure Gages	Electronic	Pneumatic Mechanical	Pneumatic Mechanical	Pneumatic Mechanical	Substantially Equivalent
Gas Mixer	Electronic	Pneumatic Mechanical	Pneumatic Mechanical	Pneumatic Mechanical	Substantially Equivalent
Auxiliary Oxygen	No Blender	No Blender	No Blender	Blender	**SAFETY FEATURE** The Oricare A9800 Anesthesia Workstation includes an Auxiliary O_2/Air Blender while the predicate devices have Auxiliary O_2 only. The A9800 . Aux O_2/Air Blender when set to 100% functions identically to the predicate device's Auxiliary O2 Flow meter. The A9800 has the additional capability of an O2/Air Blender to allow the user to lower the Auxiliary O2 level below 100%. To prevent Surgical fires where a nasal cannula or other open system is in use, lower concentrations of O2 are preferred per FDA, ASA and APSF initiatives. There is no patient risk. The A9800 is substantially equivalent to the predicate device.

5.15 Predicate Device(s) Comparison Table – AGSS

Item of comparison	GE Avance Predicate	Mindray A5 Predicate	Draeger Apollo Predicate	Oricare A9800 Current Submission	Substantial Equivalence
AGSS Type – Active	Adjustable Flow	Adjustable Flow	Adjustable Flow	Adjustable Flow	Substantially Equivalent
AGSS low flow indicator	Yes	Yes	Yes	Yes	Substantially Equivalent
AGSS connector	DISS evac	DISS evac	DISS evac	DISS evac	Substantially Equivalent

5.16 Substantial Equivalence Summary

Operational and technological characteristics form the basis for the determination of substantial equivalence of the A9800 Anesthesia workstation with the legally marketed predicate device(s) (K123125, K123211, and K042607). The A9800 is substantially equivalent to the predicate device(s).

5.17 Non-Clinical Tests – Harmonized Standards

The A9800 has passed all safety tests for demonstrated compliance with the harmonized standards below:

Standard	FDA Recognition #	Title	Testing Laboratory
IEC 60601-1	5-4	Medical equipment/medical electrical equipment - Part 1: General requirements for basic safety and essential performance	3rd Party: TUV
IEC 60601-1-2	5-35	Medical Electrical Equipment - Part 1: General requirements for safety to collateral Standard: Electromagnetic Compatibility requirements and tests.	3rd Party: National Testing and Inspection Center
IEC 60601-1-8	5-49	Medical Electrical Equipment – Part 1-8: General requirements for safety – collateral standard: Alarm Systems	3rd Party: TUV
IEC 62366	5-50	Medical Devices – Application of usability engineering to medical devices.	3rd Party: TUV
ISO 80601-2-13	Not Recognized	Medical Electrical Equipment Part 2-13: Particular Requirements for basic safety and essential performance of an anesthetic workstation.	3rd Party: TUV
IEC 60601-1-6	Not Recognized	Medical Electrical Equipment Part 1-6: General requirements for safety – collateral standard: Usability including IEC 62366: Application of usability engineering to medical devices.	3rd Party: TUV

5.18 Non-Clinical Bench Tests	
Waveform Analysis	A9800 to Avance waveform comparison report
Simulated Use Validation	Simulated Use Validation testing of anesthesia machine
Phasein	Phasein standard requirements report – EN60601-1 and 21647
ISTA	ISTA shipping test report
Gas Analyzer Test Report	A9800 Gas Analyzer report
RD-GMAP-M3-004	BDU/PSU – Main control board hardware test unit
RD-GMAP-M3-008	SBU – Sensor board hardware unit test
RD-GMAP-M3-010	KBD – Keyboard hardware unit test report
RD-GMAP-M3-014	EFM – E-flowmeter board hardware unit test report
RD-GMAP-M3-020	Integration test and prototype machine verification report
RD-GMAP-M3-042	Blender test report
RD-GMAP-M3-043	Breathing system manual/auto switch life cycle test report
RD-GMAP-M3-044	Breathing system test report to ISO8835-2
RD-GMAP-M3-047	ACGO Switch life cycle test report
RD-GMAP-M3-050	Hardware system Verification and Validation Report
RD-GMAP-M3-057	Breathing system Hi temperature steaming test report
RD-GMAP-M3-064	Breathing system heating test report
RD-GMAP-M3-066	Battery charge & discharge test report
RD-GMAP-FDA-020	AGSS Test to ISO 8835-3-2007
NAMSA-N112221	Summary Report and Biological Safety Assessment
NAMSA-V0014_130	Cytotoxicity
NAMSA-T0625_500	ISO Systemic Toxicity Study in Mice
NAMSA-TI251_800	ISO Intracutaneous Study in Rabbits
NAMSA-TI261_300	ISO Guinea Pig Maximization Sensitization Test
LSO Autoclave-SVS-ORC-01	Steam Sterilization Cycle Validation
Nelson Lab Disinfectant – 739231A	High Level Disinfection Validation Report

5.19 Summary of Non-Clinical Tests as required by 807.92 (b)(1)(3)

The A9800 Anesthesia Workstation has been thoroughly tested. FDA recognized standards, FDA guidance documents, harmonized standards, verification and validation, software validation, usability validation, and risk management activities have taken place for the A9800 Anesthesia Workstation.

The A9800 Anesthesia Workstation will be manufactured in compliance with FDA and ISO quality system requirements. System validation and verification will demonstrate that the functional requirements and system specifications have been met prior to commercial release.

Based upon the design, intended use, indications for use, classification, usability and safety testing the A9800 Anesthesia Workstation is substantially equivalent to the listed predicate device(s) (K123125, K123211, and K042607).

No new issues of safety or effectiveness are introduced as a result of using this device.

5.20 Summary of Clinical Tests as required by 807.92 (b) (1) (2)

The A9800 Anesthesia Workstation, like the predicate device, did not require clinical trials. FDA recognized standards, FDA guidance documents, harmonized standards, verification and validation, software validation, usability validation, and risk management activities have taken place for the A9800 Anesthesia Workstation.

Based upon the design, intended use, indications for use, classification, usability and safety testing the A9800 Anesthesia Workstation is substantially equivalent to the listed predicate device(s) (K123125, K123211, and K042607).

No new issues of safety or effectiveness are introduced as a result of using this device.

5.21 Conclusion

Oricare considers the A9800 Anesthesia Workstation to be substantially equivalent to the predicate device(s) **(K123125, K123211, and K042607).**

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

May 9, 2014

Oricare Incorporated
Mr. Kurtis Montegna
Quality Assurance & Regulatory Affairs Manager
1900 AM Drive
Quakerstown, PA 18951

Re: K131790
Trade/Device Name: A9800 Anesthesia Workstation
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas machine for anesthesia or analgesia
Regulatory Class: Class II
Product Code: BSZ
Dated: April 04, 2014
Received: April 10, 2014

Dear Mr. Montegna:

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" (21CFR 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,

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K131790

Device Name: A9800 Anesthesia Workstation

Indications for Use:

The A9800 Anesthesia Workstation provides general inhalation anesthesia and ventilatory support for adolescents to adults in an operating room environment. The device is indicated for volume or pressure control ventilation.

Prescription use __X__ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Todd D. Courtney -S
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