OCT 09 2008 K081670

510(k) Summary

510(k) Summary as required by 21 CFR § 807.92

510(k) Submitter:	Cardinal Health 207, Inc. Yorba Linda, CA 92887 Phone: (714) 283-8472 Fax: (714) 283-8472
Contact Person	Andre von Muller phone/fax: (714) 292-9464 email: andre.vonmuller@cardinalhealth.com
Establishment Registration Number	2050001
Date prepared	June 4, 2008
Name of the device	THE ADVANTAGE SERIES® Non-vented (NV) Full Face Mask
Common/usual name	Mask for use with ventilator (continuous, facility use)
Classification	THE ADVANTAGE SERIES® Non-vented (NV) Full Face Mask is classified as a Class II device under the following classification code:

Product Code	CFR Section	Panel
CBK	21 CFR 868.5895	Anesthesiology

Reason for the submission	This is a new device to be marketed by Cardinal Health 207, Inc.
Substantially equivalent device	THE ADVANTAGE SERIES® Non-vented (NV) Full Face Mask is substantially equivalent to the following device: ➢ Image3 SE Disposable Full Face Mask (K023135). THE ADVANTAGE SERIES® Non-vented (NV) Full Face has the following similarities to the predicate device: ➢ Same intended use ➢ Same technology Labeling for the predicate device to which substantial equivalence has been claimed is included in Section 21 of this 510(k) submission.
Device Description.	THE ADVANTAGE SERIES® Non-vented (NV) Full Face Mask provides a seal around the nose and mouth such that pressure from a positive pressure source is directed into the patient's nose and mouth. It is held in place with an adjustable headgear. The design consists of latex-free silicone cushion connected to a molded polycarbonate frame with an elbow that can swivel 360°. The elbow shall have an interconnection mating with the tubing from the positive pressure device. The interconnection shall conform to ISO 5356-1 (EN1281-1) with a 22mm female connector that can also swivel through 360°. This mask can be used to deliver positive pressure therapy to patients requiring pressures up from 3 to 40 cmH_2O. This mask can be used with a range of devices that provide a low level of pressure and that have a

	mechanism to adequately remove exhaled gases as well as a safety valve that opens to atmosphere to provide room air in the event of loss of supply pressure. THE ADVANTAGE SERIES® Non-vented (NV) Full Face Mask is functionally similar to Cardinal Health Advantage Series Full Face mask (K043382) except that it does not have the anti-asphyxia or an exhalation port. Due to the fact that this is a non-vented mask, there is a need for a separate mechanism to remove exhaled gases. Reference Section 22 of this submission for a drawing of the mask.
Intended Use/Indications for Use	THE ADVANTAGE SERIES® Non-vented (NV) Full Face Mask is intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to ventilators which have adequate alarms and safety systems for ventilator failure, and which are intended to administer CPAP or positive pressure ventilation for treatment of respiratory failure, respiratory insufficiency, or obstructive sleep apnea. The mask is disposable and for single patient use. It is for use on adult patients (> 30 kg), who are appropriate candidates for noninvasive ventilation and use in a hospital/institutional environment.
Comparison of technological characteristics between devices.	THE ADVANTAGE SERIES® Non-vented (NV) Full Face Mask is functionally similar to the Cardinal Health Advantage Series Full Face mask (K043382) except that it does not have the anti-asphyxia or an exhalation port. It is constructed from the same materials as the Advantage Series Full Face Mask. THE ADVANTAGE SERIES® Non-vented (NV) Full Face Mask is substantially equivalent to the Image3 SE Disposable Full Face Mask (K023135). A comparison of the Advantage Full-Face Non-Vented (NV) Mask to the Image3 SE Disposable Full Face Mask has been provided in Section 12 of this 510(k) submission.
Summary of non-clinical performance testing.	THE ADVANTAGE SERIES® Non-vented (NV) Full Face Mask was tested under various conditions using the Cardinal Health design control process to evaluate design parameters. Testing included: • Conformance to design specifications • Interconnection to patient circuit compliant with international standards • Environmental testing • Dead Space • Pressure vs. Flow • Leak Allowance • Cleaning The mask passed the specified test criteria.
Summary of clinical performance experience.	THE ADVANTAGE SERIES® Non-vented (NV) Full Face Mask was not subjected to human clinical studies to validate the performance of the device.
Conclusion	The bench performance data of the ADVANTAGE SERIES® Non-vented (NV) Full Face Mask, when compared to the data and/or claims made on the predicate devices, demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate devices. The intended use of the ADVANTAGE SERIES® Non-vented (NV) Full Face Mask is the same as the predicate device. No new questions of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 09 2008

Mr. Andre von Muller
Senior Regulatory Affairs Engineer
Cardinal Health 207, Incorporated
22745 Savi Ranch Parkway
Yorba Linda, California 92887

Re: K081670
Trade/Device Name: ADVANTAGE SERIES® Non-vented (NV) Full Face Mask
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: September 26, 2008
Received: September 29, 2008

Dear Mr. von Muller:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Samuel Lin for

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081670

Device Name: ADVANTAGE SERIES® Non-vented (NV) Full Face Mask

Indications for Use: The ADVANTAGE SERIES® Non-vented (NV) Full Face Mask is intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to ventilators which have adequate alarms and safety systems for ventilation failure and which are intended to administer CPAP or positive pressure ventilation for treatment of respiratory failure, respiratory insufficiency, or obstructive sleep apnea.

The mask is disposable and for single patient use. It is for use on adult patients (>30 kg) who are appropriate candidates for noninvasive ventilation and use in a hospital/institutional environment.

Prescription Use ✔ AND/OR Over the Counter Use _____
(Part 21 CFR 801 Subpart D) (21CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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