DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

CareFusion 213 LLC
% Arlen Johnson
Sr. Regulatory Affairs Specialist
1550 Northwestern Drive
El Paso, Texas 79912

MAR 30 2011

Re: K103106
Trade/Device Name: ChloraShield™ Antimicrobial Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 17, 2011
Received: March 21, 2011

Dear Arlen Johnson:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K 103106

Device Name: ChloraShield™ Antimicrobial Dressing

Indications for use:

The ChloraShield™ Antimicrobial Dressing is intended for use as a wound dressing to absorb exudate and to cover and protect catheter sites. Common applications include IV catheters, other intravascular catheters and percutaneous devices.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use		AND/OR	Over-The-Counter Use	
	X			

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103106

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

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Date: March 18, 2010

Submitter:
CareFusion 213 LLC
1550 Northwestern Drive
El Paso, TX 79912

Primary Contact Person:
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Device Trade Name: ChloraShield™ Antimicrobial Dressing

Common Trade Name: Antimicrobial Dressing

Classification: Unclassified

Panel: General, Restorative, and Neurological Devices

Product Code (Primary): FRO

Predicate Devices: Two predicate devices are identified in this submission:

	510(k) #	Date of Clearance	Company
1	K003229	10-26-2001	Integra Lifesciences
2	K063458	4-5-2007	3M

Device Description: The ChloraShield™ Antimicrobial Dressing is intended to fill the need for a transparent primary catheter dressing that can be applied easily while surrounding the wound site.

The dressing is an oval shaped dressing intended to cover and protect a catheter site and absorb exudates.

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Device Description:	The dressing is transparent and conformable allowing for easy visual and manual inspection of IV sites. The dressing is impregnated with Chlorhexidine Gluconate (CHG), a persistent, broad spectrum antimicrobial and antifungal activity against a wide range of gram positive and gram negative organisms. The antimicrobial agent protects the dressing from bacterial penetration and colonization. The patch complements other infection control measures by providing continued IV site protection while also allowing for good site visualization and inspection. ChloraShield has not been clinically tested for its ability to reduce local infections, catheter-related blood stream infections (CRBSI) or skin colonization of microorganisms commonly related to CRBSI. The product is sold in a sterile condition, opened in the operating field and then applied to the catheter site. Like the predicate devices, the ChloraShield™ Dressing is easy to apply and easy to remove. The product offering includes: The product number is: # 410100 standard package – one dressing or patch per sterile package.
Intended Use:	The ChloraShield™ Antimicrobial Dressing is intended for use as a wound dressing to absorb exudate and to cover and protect catheter sites. Common applications include IV catheters, other intravascular catheters and percutaneous devices.
Technology:	The proposed device is similar to the predicate devices and uses biocompatible materials that are merged into a dressing that is breathable, transparent and easy to apply and remove. The device consists of a polypropylene mesh that holds or has been imbibed with a proprietary hydrogel that contains the active ingredient. The product is supplied in a sterile condition with one product per foil laminate pouch.
Determination of Substantial Equivalence:	<u>Summary of Non-Clinical Tests:</u> A variety of non-clinical tests were conducted to show the safety and effectiveness of the proposed device including

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the use of placebos and, comparisons against the predicate devices including tests on mice, rabbits and guinea pigs. Standardized test methods from ASTM and ISO were used in this testing and are described in the submission.

Determination of Substantial Equivalence:

Summary of Clinical Tests:
A clinical study was conducted which compared the tolerability (frequency and severity of skin reactions) at skin sites across a wear period of seven days. Forty-five subjects participated in the study (15 subjects per treatment group).

The safety assessment in the clinical study was designed to evaluate if an exaggerated use model would cause irritation or adverse events in normal healthy volunteers when receiving multiple test article applications over a seven-day duration of exposure. The study design employed an initial high dose exposure, (7 times the exposure of the intended clinical use), on Day 1 and daily descending exposure of one patch each day over the 7 day wear period.

The tolerability of the proposed device was found to be equivalent to the predicate devices and additional detail is provided in the submission.

Standards Used in the Testing and Development of this Product:

- ISO 11607-2:2006. Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes
- ISO 11135-1:2007. Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ISO 10993-7:1995 (R) 2001. Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
- ASTM D4169 - 09 Standard Practice for Performance Testing of Shipping Containers and Systems

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In accordance with 21 CFR 807.92 the following summary of information is provided:

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- ASTM D4728 - 06 Standard Test Method for Random Vibration Testing of Shipping Containers

Standards Used in the Testing and Development of this Product:

CLSI (Clinical and Laboratory Standards Institute):

- Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard – Ninth Edition; M2-A9: Sept. 2006
- Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard – Tenth Edition; M2-A10: Jan 2009

Conclusion: The applicant considers the ChloraShield™ Antimicrobial Dressing to be safe and effective, and its performance is substantially equivalent to the two predicate devices.