DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20832/ S-29

APPROVAL LETTER

CareFusion 213 LLC
Attention: Carolyn E. Lindsey, RAC
Manager, Regulatory Affairs
11400 Tomahawk Creek Parkway, Suite 310
Leawood, KS 66211

Dear Ms. Lindsey:

Please refer to your Supplemental New Drug Application (sNDA) dated August 31, 2012, received September 5, 2012 pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ChloraPrep (Chlorhexidine gluconate/ isopropyl alcohol) Solution, 2% w/v/ 70% v/v

The August 31, 2012, submission constituted a complete response to our March 1, 2012, action letter.

This Prior Approval supplemental new drug application provides for: redesign ChloraPrep applicator body to reduce the possibility for glass penetrating the foam sponge after activation.

We have completed our review of this supplemental new drug application. This supplement is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call LCDR Luz E Rivera, Regulatory Project Manager, at (301) 796 4013.

Sincerely,

{See appended electronic signature page}

Eric Duffy, PhD
Division Director
Division of New Drug Quality Assessment III
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SWAPAN K DE
12/27/2012
Signed for Eric Duffy