

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Indications for Use

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See PRA Statement on last page.

510(k) Number (if known)

K200614

Device Name

FiteBac® Antimicrobial Cavity Cleanser

Indications for Use (Describe)

The FiteBac® Antimicrobial Cavity Cleanser with 2% K21 QAS is an antimicrobial aqueous ethanolic solution intended for cleansing and moistening/re-wetting of cavity preparations.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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