

Comments on the Classification of Wound Care Products with Drugs

*Meeting of the FDA's General and Plastic Surgery Devices Panel of the
Medical Devices Advisory Committee
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Background Information

- I am the Vice President of Global Regulatory Affairs with over 30 years experience with medical devices specifically with regenerative and wound care medical devices, principally Class III and Class II Medical Devices
- Integra LifeSciences is a global leader in Medical Devices in the areas of Regenerative Technologies, Orthopedics, Neurosurgery, NeuroTrauma and Surgical Instruments
- Integra manufactures several products that are wound dressings with drugs in the FRO Category
- My participation in this meeting is being sponsored by Integra LifeSciences Corporation

Key Points for Discussion:

- **The 510(k) Premarket Notification process has demonstrated to be an effective process to regulate the wound dressings combined with drugs in the FRO category.**
- **Wound dressings combined with drugs are used for the management of wounds not the treatment of wounds or treatment of infections.**
- **There are wound dressings combined with drugs that have significant level of clinical experience including clinical trial and articles published in peer reviewed journals regarding safe and effective use.**
- **It is recommended that an FDA Guidance document regarding Special Controls and contents of the 510(k) Premarket Notification process for wound dressings combined with drugs be developed.**

The 510(k) Process for Wound Dressings with Drugs

- **There are over 500 wound dressings combined with drugs in the FRO category that have been cleared by the 510(k) Premarket Notification process**
- **Wound Dressings combined with drugs regulated in the FRO category in general have indications for use for the management of wounds and not indicated for the treatment of wounds.**
- **Many of the medical devices in the FRO category have been regulated under the 510(k) Premarket Notification process for over 25 years.**
 - **There is a long history of safe and effective use**

Significant Clinical Benefit:

Specifically:

- **There are wound dressings with chlorhexidine that are cleared for use for the indication to reduce catheter related bloodstream infection.**
- **The CDC Guidelines recommend the use of chlorhexidine impregnated sponge dressings for temporary short-term catheters in patients older than two(2) months of age.**
- **Clinical Trial results and articles in peer reviewed journals have established the safe and effective use of wound dressings with chlorhexidine to reduce the incidence of catheter related bloodstream infection.**

- **The 510(k) Premarket Notification Submission Process is an appropriate Regulatory pathway for wound dressings with drugs predicate device**
 - **The goal of a 510(k) submission is to demonstrate substantial equivalence to a device that is already legally marketed**
 - **Device is substantially equivalent (SE) to another device if it has the same intended use**
 - **and either the same technological characteristics or**
 - **different technological characteristics but is as safe and effective as the other device**
 - **technological characteristics refer to items such as the design of a device, its materials and its energy source**
 - **does not raise different questions of safety or effectiveness (FDCA § 513(I)(1)(A)g.)**

Data Included in a 510(k):

- **Complete Device Description**
- **Substantial Equivalence to Predicate Devices**
- **Labeling, Information for use, for the Device**
- **Biocompatibility Studies in compliance with ISO 10993**
 - **Cytotoxicity**
 - **Primary Skin Irritation Study**
 - **Acute Dermal Toxicity Study**
 - **Acute Systemic Toxicity**
 - **Intracutaneous Toxicity**
 - **Sensitization Study**
 - **Chronic Toxicity Studies**
- **In Vitro Microbiology Activity**

Other data that may be included for wound dressings combined with drugs:

- **Kinetic Studies for the release of the antimicrobial from the wound dressing**
- ***In Vitro* Zone of Inhibition Studies**
- **Performance Testing – Bench Testing**
- **Performance Testing – Animal Testing**
- **Performance Testing – Clinical**
- **Risk Analysis/Risk Mitigation/Risk Management**
- **Reference to the NDA number and Drug Master File for the antimicrobial agent**

- **As outlined in FDA's Executive Summary, the General and Plastic Surgery Devices Panel held an Advisory Panel Meeting on August 25, 2005 to provide advice and recommendations to FDA on the classification of five unclassified pre-amendment devices**
- **FDA presented information on dressings that contains drugs (i.e., silver, bismuth, chlorhexidine containing wound dressings) including:**
 - **Risk of use**
 - **Risk Mitigation measures**
- **The panel voted unanimously to recommend that FDA classify wound dressings with a drug as Class II Medical Devices with special controls requiring 510(k) Premarket Notification.**
- **The 510(k) Premarket Notification for wound dressings combined with drugs is an effective Regulatory pathway for these products.**

Conclusions:

- **Wound dressings combined with drugs currently in the FRO category should be regulated as Class II Medical Devices under the 510(k) Premarket Notification process.**
- **We recommend that an FDA Guidance Document regarding wound dressings combined with drugs in the FRO category be developed in conjunction with FDA, wound care companies, clinicians, nurse practitioners to include special controls to support the indications for use and claims for these medical devices.**