

Elutia



Elutia – Antimicrobial Surgical Wound Drain
K063245

- **Antimicrobial: Silver Sulfadiazine/Hydrogel Coating;**
 - **USPTO # 2008/0063693; Cook G, et al.**

As V.P. of Business Development, Responsibilities and Contributions included:

- **Business Development: Oversaw internal *combination product* medical device product development effort and managed Corporate Client [external] antimicrobial coating programs**
- **Regulatory: re Elutia - Negotiated with FDA**
 - **Product Classification**
 - **In-vitro assay test methods**
 - **Indications for Use [IFU]**
 - **Secured Agency ‘Concurrence’**
- **Regulatory re Corporate Client Programs: Led Client/FDA Pre-submission meeting re antimicrobial Vascular Access Device**
 - **Device subsequently Agency ‘Concurred’**