



US Regulatory Calculator

Date Generated:
November 17, 2009

Technology Name: Mitral Valve Repair Device

Technology Description: New annuloplasty ring design offering unique position optimization that makes implantation easier.

Based on the information provided, the e-Zassi US Regulatory Calculator has returned the potential predicate regulation number, product code and classification(s) & regulatory pathway(s) associated with the technology.

Regulation #	Regulation Name	Product Code	Product Code Title	Classification	Regulatory Pathway
870.3800	annuloplasty ring	KRH	Ring, Annuloplasty	Class II	510(k)

This information provides insights to be shared in conversations with the FDA or regulatory consultants. To rapidly locate a specialized regulatory consultant in your technology area, run an advanced search by selecting the **Discover** feature.

To gain additional insights into other important areas such as the European Union (EU) regulatory classification; critical clinical endpoints that support the safety and marketing claims to earn market clearances; reimbursement and market landscape; and identification of manufacturing, distribution and sales burdens, it is recommended that you utilize e-Zassi's entire decision support platform for this technology. In less than an hour, you can generate a comprehensive InnoVision™ Report by selecting the **Analyze** feature.

The information presented within this document does not represent or intend to be an opinion, a suggestion, a comment, or a decision from the US Food and Drug Administration (FDA), or any of its authorities, agents, employees, or third party representatives. Ultimately, the FDA reserves responsibility for classifying a new medical device.