

Technology Name: Oximeter Catheter

Technology Description: Oximeter Catheter

From the information you have provided, e-Zassi calculated the US Food and Drug Administration (FDA) classification and other information relevant to your technology.

Regulation #	Regulation Name	Product Code	Product Code Title	Classification	Regulatory Pathway
870.1230	fiberoptic oximeter catheter	DQE	Catheter, Oximeter, Fiberoptic	Class II	510(k)
870.1230	fiberoptic oximeter catheter	NMB	Catheter, Oximeter, Fiber Optic, Reprocessed	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 arena start an advanced search by selecting the **Discover** feature at www.e-Zassi.com.

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 at www.e-Zassi.com.

For electronic access or other services contact e-Zassi customer support at 866-369-5170.

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.