

K092684 LAPAROSCOPIC RETRACTORSJan 22, 2010
143 days to decisionK092684 · Product code: **GCJ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k092684/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Sep 1, 2009
Decision date	Jan 22, 2010
Days to decision	143 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cardinal Health, Inc.
Location	Waukegan, IL, US
Contact	SHARON NICHOLS
Website	http://www.cardinalhealth.com
510(k) history	26 submissions · 26 cleared · 2006-2017

Cardinal Health, Inc. is an American multinational health care services company headquartered in Dublin, Ohio. The company specializes in pharmaceutical distribution and medical product manufacturing, serving over 100,000 locations across the United States. Cardinal Health has received FDA 510(k) clearances from total submissions between 2006 and 2017. The company's regulatory focus centers on surgical gloves and protective apparel, including sterile and powder-free formulations. This historical record reflects the company's established presence in General Hospital device...
