FDA 510(k) Premarket Notification

K160539 BiZact Open Sealer/Divider

CLEARED

Jun 15, 2016
110 days to decision

K160539 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k160539/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Feb 26, 2016
Decision date	Jun 15, 2016
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Covidien**
Location	North Haven, CT, US
Contact	Sharon McDermott
510(k) history	130 submissions · 126 cleared · 2008-2024

Covidien is an Irish-registered global healthcare products company headquartered in North Haven, Connecticut. Now part of Medtronic following a 2015 acquisition, the brand continues to operate as a major medical device manufacturer. Covidien maintains a strong FDA 510(k) regulatory record with cleared devices from total submissions spanning 2008 to 2024. The company specializes in General & Plastic Surgery devices, with a dominant focus on surgical staplers, sutures, and wound closure systems. Recent clearances include advanced stapling technologies, endotracheal tubes, a...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k160539/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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