FDA 510(k) Premarket Notification

K092191 EXILIS, MODEL 5000

CLEARED

Nov 25, 2009
127 days to decision

K092191 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k092191/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jul 21, 2009
Decision date	Nov 25, 2009
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Btl Industries, Ltd.**
Location	Austin, TX, US
Contact	RICHARD VINCINS
510(k) history	3 submissions · 3 cleared · 2009-2014