

**K981981 ELECTROSURGICAL UNIT (ESU) (115 VOLT) MODEL
4810, ELECTROSURGICAL UNIT (ESU) (230 VOLT) MODEL
4811, INSTRUMENT CABLE, 19**Sep 3, 1998
90 days to decisionK981981 · Product code: **GEI** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k981981/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jun 5, 1998
Decision date	Sep 3, 1998
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Corp
Location	San Jose, CA, US
Contact	STEVE JWANOUSKOS
Website	https://www.bostonscientific.com/
510(k) history	432 submissions · 411 cleared · 1988-2024

Boston Scientific Corp is a global medical device manufacturer headquartered in San Jose, US. The company develops and markets devices across multiple therapeutic areas including cardiovascular, gastroenterology, and surgical specialties. Boston Scientific has maintained a strong FDA 510(k) regulatory presence since 1988. The company has received FDA 510(k) clearances from total submissions. Recent clearances in 2024 demonstrate continued innovation and active market engagement across cardiovascular and gastroenterology device categories. Recent cleared devices reflect th...
