

**K092009 MODIFICATION TO: LEVEEN SUPERSLIM NEEDLE
ELECTRODES, MODELS M001262260, M001262270,
M001262280, M001262290**Nov 6, 2009
123 days to decisionK092009 · Product code: **GEI** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k092009/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jul 6, 2009
Decision date	Nov 6, 2009
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Corporation
Location	Marlborough, MA, US
Contact	JENNIFER KIMBALL
Website	https://www.bostonscientific.com
510(k) history	229 submissions · 216 cleared · 2005-2026

Boston Scientific Corporation is a global medical device manufacturer headquartered in Marlborough, Massachusetts. The company develops and markets devices across multiple medical specialties. Boston Scientific has received FDA 510(k) clearances from total submissions since its first clearance in 2005. The company maintains active regulatory engagement, with the latest clearance in 2026. Its cleared devices span cardiovascular, radiology, gastroenterology, urology, and surgical specialties, reflecting a broad portfolio of interventional and diagnostic technologies. Recent...