

**K232334 DEKA SIMON**Sep 1, 2023  
28 days to decisionK232334 · Product code: **IPF** · Physical MedicineSource: <https://www.510kdatabase.net/k232334/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Aug 4, 2023
Decision date	Sep 1, 2023
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>El.En S.P.A.</b>
Location	Hopkinton, MA, US
Contact	Paolo Peruzzi
510(k) history	15 submissions · 15 cleared · 2014-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232334/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026