

**K201958 ETD Family of Electrotherapy Devices**Aug 4, 2020  
21 days to decisionK201958 · Product code: **IPF** · Physical Medicine  
Source: <https://www.510kdatabase.net/k201958/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Jul 14, 2020
Decision date	Aug 4, 2020
Days to decision	21 days
Third-party review	Yes
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Therasigma, LLC</b>
Location	Washougal, WA, US
Contact	Jim Klett
510(k) history	2 submissions · 2 cleared · 2020-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201958/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026