

K812538 ELITEDec 1, 1981
89 days to decisionK812538 · Product code: **IPF** · Physical Medicine
Source: <https://www.510kdatabase.net/k812538/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Sep 3, 1981
Decision date	Dec 1, 1981
Days to decision	89 days
Third-party review	No

APPLICANT

Company	Biotone International, Inc.
Location	Mchenry, IL, US
510(k) history	4 submissions · 4 cleared · 1981-1982

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Device record: <https://www.510kdatabase.net/k812538/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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