

**K943185 BX-200 SC**Aug 14, 1995  
489 days to decisionK943185 · Product code: **IPF** · Physical MedicineSource: <https://www.510kdatabase.net/k943185/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Apr 12, 1994
Decision date	Aug 14, 1995
Days to decision	489 days
Third-party review	No

**APPLICANT**

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Company	<b>Bloomex International, Inc.</b>
Location	Mchenry, IL, US
Contact	BENJAMIN LAROUX
510(k) history	16 submissions · 14 cleared · 1979-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k943185/>; 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 22, 2026