

**K220994 Shoulder PacemakerTM**Oct 14, 2022  
193 days to decisionK220994 · Product code: **IPF** · Physical Medicine  
Source: <https://www.510kdatabase.net/k220994/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Apr 4, 2022
Decision date	Oct 14, 2022
Days to decision	193 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ncs Lab Srl</b>
Location	Carpi, IT
Contact	Matteo Mantovani
510(k) history	4 submissions · 4 cleared · 2012-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mcra, LLC</b>
Contact	Tim Marjenin

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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