

**K240564 NuFACE® FIX+**Jun 27, 2024  
119 days to decisionK240564 · Product code: **NFO** · Neurology  
Source: <https://www.510kdatabase.net/k240564/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Transcutaneous Electrical, Aesthetic Purposes (NFO)
Date received	Feb 29, 2024
Decision date	Jun 27, 2024
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Carol Cole Company Db a Nuface</b>
Location	Vista, CA, US
Contact	Robert Castro
510(k) history	8 submissions · 8 cleared · 2017-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k240564/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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