

**K214037 Ergo-Flex Technologies Back on Trac (BOTGEN1) and Cervi-Trac**Feb 22, 2024  
791 days to decisionK214037 · Product code: **ITH** · Physical Medicine  
Source: <https://www.510kdatabase.net/k214037/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Equipment, Traction, Powered (ITH)
Date received	Dec 23, 2021
Decision date	Feb 22, 2024
Days to decision	791 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ergo-Flex Technologies, LLC</b>
Location	Conroe, TX, US
Contact	Linda Anderson
510(k) history	1 submissions · 1 cleared · 2024-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Texas Applied Biomedical Services</b>
Contact	M. Joyce Heinrich

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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