

**K251594 truFlex**Aug 28, 2025  
93 days to decisionK251594 · Product code: **NGX** · Physical MedicineSource: <https://www.510kdatabase.net/k251594/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                         |
| Submission type       | Special  |
| Device classification | Stimulator, Muscle, Powered, For Muscle Conditioning (NGX) |
| Date received         | May 27, 2025   |
| Decision date         | Aug 28, 2025   |
| Days to decision      | 93 days  |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Syrma Johari Medtech Limited</b>   |
| Location       | Jodhpur, IN                           |
| Contact        | Sabyasachi Nath                       |
| 510(k) history | 1 submissions · 1 cleared · 2025-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251594/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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