

**K202492 EZ-IO Intraosseous Vascular Access System**Mar 22, 2021  
203 days to decisionK202492 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k202492/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)     |
| Submission type       | Traditional                            |
| Device classification | Needle, Hypodermic, Single Lumen (FMI) |
| Date received         | Aug 31, 2020                           |
| Decision date         | Mar 22, 2021                           |
| Days to decision      | 203 days                               |
| Third-party review    | No                                     |
| Combination product   | No                                     |
| PCCP authorized       | No                                     |
| Summary / Statement   | Summary                                |

**APPLICANT**

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|----------------|---|
| Company        | <b>Teleflex Medical</b>                 |
| Location       | Fall River, MA, US                      |
| Contact        | Rachel Rehl                             |
| 510(k) history | 39 submissions · 39 cleared · 2003-2025 |

Teleflex Medical is an American medical device company headquartered in Wayne, Pennsylvania, with operations in Fall River, US. The company is a major provider of specialty medical devices for critical care and surgical procedures. Teleflex Medical has received FDA 510(k) clearances from total submissions since 2003. The company maintains active regulatory engagement, with the latest clearance in 2025. Its cleared devices span multiple specialties including anesthesiology, general and plastic surgery, cardiovascular, and vascular access systems. The company's product port...