

**K121124 ARTHREX MIXING AND DELIVERY SYSTEM**May 16, 2012  
33 days to decisionK121124 · Product code: **FMF** · General Hospital  
Source: <https://www.510kdatabase.net/k121124/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Syringe, Piston (FMF)              |
| Date received         | Apr 13, 2012                       |
| Decision date         | May 16, 2012                       |
| Days to decision      | 33 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Arthrex, Inc.</b>  |
| Location       | Naples, FL, US  |
| Contact        | CHRISTINA FLORES  |
| Website        | <a href="https://www.arthrex.com">https://www.arthrex.com</a> |
| 510(k) history | 346 submissions · 342 cleared · 1992-2026                     |

Arthrex, Inc. is a medical device manufacturer based in Naples, US. The company specializes in surgical implants and instruments for orthopedic procedures. Arthrex has received FDA 510(k) clearances from total submissions since its first clearance in 1992. The company's portfolio is dominated by Orthopedic devices, which represent 89% of its regulatory submissions. Recent cleared devices include suture anchors, plating systems, nails, and specialized fixation devices for shoulder, ankle, and lower extremity procedures. The latest FDA 510(k) clearance was received in 2026,...

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