FDA 510(k) Premarket Notification

# K243407 Forcyte Autograft Harvest Kit

**CLEARED**

Jul 29, 2025
270 days to decision

K243407 · Product code: **KNW** · Orthopedic
Source: https://www.510kdatabase.net/k243407/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Instrument, Biopsy (KNW) |
| Date received | Nov 1, 2024 |
| Decision date | Jul 29, 2025 |
| Days to decision | 270 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Forcyte Medical, LLC** |
| Location | Marietta, GA, US |
| Contact | Robert Assell |
| 510(k) history | 1 submissions · 1 cleared · 2025-2025 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Wagoner Consulting, LLC** |
| Contact | Cheryl Wagoner |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov