

K213958 Bioabsorbable AnchorApr 8, 2022
112 days to decisionK213958 · Product code: **MAI** · Orthopedic
Source: <https://www.510kdatabase.net/k213958/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Fastener, Fixation, Biodegradable, Soft Tissue (MAI) |
| Date received | Dec 17, 2021 |
| Decision date | Apr 8, 2022 |
| Days to decision | 112 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Embody, Inc. |
| Location | Norfolk, VA, US |
| Contact | Brianna Schehr |
| 510(k) history | 6 submissions · 6 cleared · 2020-2025 |

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