

K254077 OSSIOfiber® Threaded Trimmable Fixation NailMay 1, 2026
134 days to decisionK254077 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k254077/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Screw, Fixation, Bone (HWC) |
| Date received | Dec 18, 2025 |
| Decision date | May 1, 2026 |
| Days to decision | 134 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | OSSIO , Ltd. |
| Location | Caesarea, IL |
| Contact | Taly Lindner |
| Website | https://ossio.com |
| 510(k) history | 20 submissions · 20 cleared · 2019-2026 |

OSSIO, Ltd. specializes in orthopedic fixation and soft tissue repair devices. The company operates with a manufacturing facility in Caesarea, IL. OSSIO has received FDA 510(k) clearances from total submissions since 2019. The company's portfolio focuses entirely on orthopedic solutions, including fixation nails, suture anchors, interference screws, and compression staples. The latest clearance in 2026 reflects continued regulatory activity and product development. OSSIO's OSSIOfiber® product family represents the company's core technology platform for orthopedic fixation...

REGULATORY CONSULTANT

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|-----------------|------------------|
| Consulting firm | Mcra, LLC |
| Contact | Dave McGurl |

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

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Device record: <https://www.510kdatabase.net/k254077/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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