

K211324 2.4mm Distal Radius SystemMar 14, 2022
318 days to decisionK211324 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k211324/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Plate, Fixation, Bone (HRS) |
| Date received | Apr 30, 2021 |
| Decision date | Mar 14, 2022 |
| Days to decision | 318 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Auxein Medical Private Limited |
| Location | Sonipat, IN |
| Contact | Gaurav Luthra |
| 510(k) history | 12 submissions · 12 cleared · 2020-2023 |

REGULATORY CONSULTANT

| | |
|-----------------|----------------------------------|
| Consulting firm | Auxein Medical Pvt., Ltd. |
| Contact | Gaurav Luthra |

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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