

K211074 Unvers Revers Modular Glenoid System, Standard Augment Baseplates

Sep 2, 2021
143 days to decisionK211074 · Product code: PHX · Orthopedic
Source: <https://www.510kdatabase.net/k211074/>

SUBMISSION DETAILS

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Shoulder Prosthesis, Reverse Configuration (PHX) |
| Date received | Apr 12, 2021 |
| Decision date | Sep 2, 2021 |
| Days to decision | 143 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Arthrex, Inc. |
| Location | Naples, FL, US |
| Contact | Ivette Galmez |
| Website | https://www.arthrex.com |
| 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,...