

K213115 CHENA-C Spacer SystemDec 6, 2021
70 days to decisionK213115 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k213115/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Intervertebral Fusion Device With Bone Graft, Cervical (ODP) |
| Date received | Sep 27, 2021 |
| Decision date | Dec 6, 2021 |
| Days to decision | 70 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Kahtnu Surgical, Inc. |
| Location | Soldotna, AK, US |
| Contact | Craig Wilcox |
| 510(k) history | 2 submissions · 2 cleared · 2020-2021 |

REGULATORY CONSULTANT

| | |
|-----------------|------------------------|
| Consulting firm | MRC Global, LLC |
| Contact | Ann Dunahoo |

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213115/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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