

**K213069 CoLink NeoFuse Plating System**Dec 13, 2021  
81 days to decisionK213069 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k213069/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Sep 23, 2021
Decision date	Dec 13, 2021
Days to decision	81 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>In2bones USA, LLC</b>
Location	Memphis, TN, US
Contact	Christine Scifert
510(k) history	25 submissions · 25 cleared · 2016-2024

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213069/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026