

**K190842 Comus Locking Plate systems**Feb 3, 2020  
308 days to decisionK190842 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k190842/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Apr 1, 2019
Decision date	Feb 3, 2020
Days to decision	308 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Jiangsu Trauhui Medical Instrument Co., Ltd.</b>
Location	Changzhou, CN
Contact	Zhou Yu
510(k) history	2 submissions · 2 cleared · 2018-2020

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Guangzhou Osmunda Medical Device Consulting Co., Ltd.</b>
Contact	Mike Gu

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190842/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 28, 2026