

**K182416 NOVA Minimally Invasive System**Jun 11, 2019  
280 days to decisionK182416 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k182416/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)            |
| Submission type       | Abbreviated                                   |
| Device classification | Thoracolumbosacral Pedicle Screw System (NKB) |
| Date received         | Sep 4, 2018                                   |
| Decision date         | Jun 11, 2019                                  |
| Days to decision      | 280 days                                      |
| Third-party review    | No  |
| Summary / Statement   | Summary                                       |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Baui Biotech Co., Ltd.</b>         |
| Location       | New Taipei City, TW                   |
| Contact        | Herman Jhan                           |
| 510(k) history | 5 submissions · 5 cleared · 2017-2024 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182416/> 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 26, 2026