

K200267 LOSPA® IS™ Spinal Fixation SystemMar 6, 2020
32 days to decisionK200267 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k200267/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Thoracolumbosacral Pedicle Screw System (NKB) |
| Date received | Feb 3, 2020 |
| Decision date | Mar 6, 2020 |
| Days to decision | 32 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Corentec Co., Ltd. |
| Location | West Cadwell, NJ, US |
| Contact | Sungwon Yang |
| 510(k) history | 33 submissions · 33 cleared · 2010-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200267/> Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026