

K253802 KHEIRON® Spinal Fixation System, including patient specific K-ROD

Jul 1, 2026  
215 days to decision

K253802 · Product code: NKB · Orthopedic  
Source: <https://www.510kdatabase.net/k253802/>

SUBMISSION DETAILS

|                       |                                               |
|-----------------------|-----------------------------------------------|
| Decision              | Substantially Equivalent (Cleared)            |
| Submission type       | Special                                       |
| Device classification | Thoracolumbosacral Pedicle Screw System (NKB) |
| Date received         | Nov 28, 2025                                  |
| Decision date         | Jul 1, 2026                                   |
| Days to decision      | 215 days                                      |
| Third-party review    | No                                            |
| Summary / Statement   | Summary                                       |

APPLICANT

|                |                                         |
|----------------|-----------------------------------------|
| Company        | S.M.A.I.O                               |
| Location       | Saint-Priest, FR                        |
| Contact        | Jean-Charles Roussouly                  |
| 510(k) history | 11 submissions · 11 cleared · 2020-2026 |

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)  
Device record: <https://www.510kdatabase.net/k253802/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).  
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