FDA 510(k) Premarket Notification

# K162134 ENNOVATE Spinal System

**CLEARED**

Dec 14, 2016
135 days to decision

K162134 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k162134/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Thoracolumbosacral Pedicle Screw System (NKB) |
| Date received | Aug 1, 2016 |
| Decision date | Dec 14, 2016 |
| Days to decision | 135 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Aesculap Implant Systems, LLC** |
| Location | Center Valley, PA, US |
| Contact | Paul Amudala |
| 510(k) history | 22 submissions · 22 cleared · 2010-2022 |