

**K160865 Model 6100C Series Single-Patient Use, Disposable Pulse Oximeter Sensors (6100C Series: 6100CA, 6100CP, 6100CI, 6100CN), Model 6101C Series Single-Patient Use, Disposable Pulse Oximeter Sensors (6101C Series: 6101CA, 6101CP, 6101CI, 6101CN), Model 6102C Series Single-Patient Use, Disposable Pulse Oximeter Sensors (6102C Series: 6102CA, 6102CP, 6102CI, 6102CN), Model 8100AA/8100AP Reusable, Finger Clip Pulse Oximeter Sensor, Model 8101AA/8101AP Reusable, Finger Clip Pulse Oximeter Senso**

Aug 5, 2016  
128 days to decision

K160865 · Product code: **DQA** · Anesthesiology  
Source: <https://www.510kdatabase.net/k160865/>

**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Oximeter (DQA)                     |
| Date received         | Mar 30, 2016                       |
| Decision date         | Aug 5, 2016                        |
| Days to decision      | 128 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Nonin Medical, Inc.</b>              |
| Location       | White Bear Lake, MN, US                 |
| Contact        | NANCY E. DEANGELO                       |
| 510(k) history | 50 submissions · 50 cleared · 1986-2024 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k160865/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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