

**K202543 OmniWire Pressure Guide Wire, 185 cm Straight Tip,  
OmniWire Pressure Guide Wire, 185 cm J-Tip**

Sep 28, 2020  
26 days to decision

K202543 · Product code: **DQX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k202543/>

**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Special                            |
| Device classification | Wire, Guide, Catheter (DQX)        |
| Date received         | Sep 2, 2020                        |
| Decision date         | Sep 28, 2020                       |
| Days to decision      | 26 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>Volcano Corporation</b>              |
| Location       | Rancho Cordova,, CA, US                 |
| Contact        | Patrick Juarez                          |
| 510(k) history | 55 submissions · 55 cleared · 2005-2021 |

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

Device record: <https://www.510kdatabase.net/k202543/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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