

K070212 CITOP10 GUIDEWIRE, 0.014(1.4MM TIP), CITOP6 GUIDEWIRE, 0.014(1.0MM TIP), CITOP SUPPORT ACCESSORY, 0.023(126CM)

Oct 12, 2007
263 days to decision

K070212 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k070212/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Jan 22, 2007
Decision date	Oct 12, 2007
Days to decision	263 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ovalum , Ltd.
Location	Rehovot, IL
Contact	KEN RAICHMAN
510(k) history	1 submissions · 1 cleared · 2007-2007

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Device record: <https://www.510kdatabase.net/k070212/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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