

K041380 IMAGECHECKER-CT SOFTWARE PACKAGE WITH FILLING DEFECT INDICATORJun 8, 2004
14 days to decisionK041380 · Product code: **OEB** · Radiology
Source: <https://www.510kdatabase.net/k041380/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lung Computed Tomography System, Computer-aided Detection (OEB)
Date received	May 25, 2004
Decision date	Jun 8, 2004
Days to decision	14 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	R2 Technology, Inc.
Location	Sunnyvale, CA, US
Contact	Kathy O'Shaughnessy
510(k) history	5 submissions · 5 cleared · 2002-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k041380/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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