

K160204 BSD4343 Digital Flat Panel X-ray DetectorJun 9, 2016
133 days to decisionK160204 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k160204/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Jan 28, 2016
Decision date	Jun 9, 2016
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bontech, Inc.
Location	Suwon-Si, KR
Contact	Kwang S. Choi
510(k) history	3 submissions · 3 cleared · 2016-2017

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