

K130377 KRYSTALRAD NEW SERIESDIGITAL RADIOGRAPHIC PORTABLE RETROFIT SYSTEM

May 17, 2013
92 days to decision

K130377 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k130377/>

SUBMISSION DETAILS

| | |
|-----------------------|------------------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Solid State X-ray Imager (flat Panel/digital Imager) (MQB) |
| Date received | Feb 14, 2013 |
| Decision date | May 17, 2013 |
| Days to decision | 92 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Medicatech USA |
| Location | Deer Field, IL, US |
| Contact | DANIEL KAMM, P.E. |
| 510(k) history | 9 submissions · 9 cleared · 2008-2023 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k130377/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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