

K120380 SATURN 8000Mar 9, 2012
31 days to decisionK120380 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k120380/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Solid State X-ray Imager (flat Panel/digital Imager) (MQB) |
| Date received | Feb 7, 2012 |
| Decision date | Mar 9, 2012 |
| Days to decision | 31 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | New Medical Co., Ltd. |
| Location | Taipei, TW |
| Contact | JUN-HSIUNG LIN |
| 510(k) history | 6 submissions · 6 cleared · 2007-2012 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k120380/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 17, 2026