

**K973329 SHIMADZU WHOLE BODY X-RAY COMPUTED  
TOMOGRAPHY SCANNER SCT-6800TX**Oct 8, 1997  
34 days to decisionK973329 · Product code: **JAK** · Radiology  
Source: <https://www.510kdatabase.net/k973329/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)        |
| Submission type       | Traditional                               |
| Device classification | System, X-ray, Tomography, Computed (JAK) |
| Date received         | Sep 4, 1997                               |
| Decision date         | Oct 8, 1997                               |
| Days to decision      | 34 days                                   |
| Third-party review    | No  |
| Summary / Statement   | Statement                                 |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>Shimadzu Medical Systems</b>         |
| Location       | Gardena, CA, US                         |
| Contact        | MICHAEL FISHBACK                        |
| 510(k) history | 90 submissions · 90 cleared · 1989-2008 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k973329/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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