

**K170832 Ultimax-i, DREX-UI80 V1.60**Jul 21, 2017  
123 days to decisionK170832 · Product code: **OWB** · Radiology  
Source: <https://www.510kdatabase.net/k170832/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Mar 20, 2017
Decision date	Jul 21, 2017
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Toshibamedical Systems Corporation</b>
Location	Tustin, CA, US
Contact	Paul Biggins
510(k) history	80 submissions · 80 cleared · 2004-2018

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k170832/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 16, 2026