FDA 510(k) Premarket Notification

K170832 Ultimax-i, DREX-UI80 V1.60

CLEARED

Jul 21, 2017
123 days to decision

K170832 · 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	**Toshibamedical Systems Corporation**
Location	Tustin, CA, US
Contact	Paul Biggins
510(k) history	80 submissions · 80 cleared · 2004-2018