

**K013371 UBIT-IR300 INFRARED SPECTROMETRY SYSTEM**Dec 21, 2001  
71 days to decisionK013371 · Product code: **JJQ** · Microbiology  
Source: <https://www.510kdatabase.net/k013371/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colorimeter, Photometer, Spectrophotometer For Clinical Use (JJQ)
Date received	Oct 11, 2001
Decision date	Dec 21, 2001
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Otsuka Pharmaceutical Co., Ltd.</b>
Location	Rockville, MD, US
Contact	CYNTHIA A SINCLAIR
Website	<a href="http://www.otsuka.co.jp">http://www.otsuka.co.jp</a>
510(k) history	6 submissions · 6 cleared · 1999-2010

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013371/> 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 June 21, 2026