

**K162387 U-IGNITE Bladeless Trocar**Jan 11, 2017  
139 days to decisionK162387 · Product code: **GCJ** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k162387/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Aug 25, 2016
Decision date	Jan 11, 2017
Days to decision	139 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Tianjin Uwell Medical Device Manufacturing Co., Ltd.</b>
Location	Tianjin, CN
Contact	TAO FAN
510(k) history	2 submissions · 2 cleared · 2016-2017

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162387/> 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 2, 2026