

**K072684 MONDEAL ENDOSCOPIC TISSUE RECESSION AND  
RELEASE SYSTEM**Jan 4, 2008  
105 days to decisionK072684 · Product code: **OCZ** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k072684/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Grasping/cutting Instrument, Non-powered (OCZ)
Date received	Sep 21, 2007
Decision date	Jan 4, 2008
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Mondeal North America, Inc.</b>
Location	San Diego, CA, US
Contact	JAY EVANS
510(k) history	1 submissions · 1 cleared · 2008-2008

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k072684/> Data sourced from FDA 510(k) public records (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. - Generated June 26, 2026