

**K083077 ULC SPINAL PEDICLE SCREW SYSTEM**Oct 26, 2009  
375 days to decisionK083077 · Product code: **MNH** · Orthopedic  
Source: <https://www.510kdatabase.net/k083077/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Oct 16, 2008
Decision date	Oct 26, 2009
Days to decision	375 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Otis Biotech Co., Ltd.</b>
Location	Siheung-Si, Gyeonggi-Do, KR
Contact	JISUK YOO
510(k) history	3 submissions · 3 cleared · 2009-2017

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