

**K081747 MODIFICATION TO SYNTHES (USA) CONDYLAR  
HEAD ADD-ON SYSTEM**Sep 5, 2008  
78 days to decisionK081747 · Product code: **NEI** · Dental  
Source: <https://www.510kdatabase.net/k081747/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Condyle, Mandibular, Temporary (NEI)
Date received	Jun 19, 2008
Decision date	Sep 5, 2008
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Synthes (Usa)</b>
Location	Mchenry, IL, US
Contact	ANDREA M TASKER
510(k) history	411 submissions · 394 cleared · 1977-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k081747/>; 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 May 14, 2026