

**K963357 MODIFICATION TO THE SYNTHES (USA) UNIVERSAL SPINAL HOOK, ROD, AND AND SACRAL SCREW FIXATION SYSTEM IN 316L STAINLESS STE**

Jan 9, 1997  
136 days to decision

K963357 · Product code: **MNH** · Orthopedic  
Source: <https://www.510kdatabase.net/k963357/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Aug 26, 1996
Decision date	Jan 9, 1997
Days to decision	136 days
Third-party review	No

**APPLICANT**

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Company	<b>Synthes (Usa)</b>
Location	Mchenry, IL, US
Contact	DIANE T BROWN
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/k963357/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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