

**K950864 GTS GREAT TOE SYSTEM - (METATARSAL COMPONENT WITH POROUS COATING)**Jul 31, 1995  
154 days to decisionK950864 · Product code: LZJ · Orthopedic  
Source: <https://www.510kdatabase.net/k950864/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Toe (metatarsophalangeal), Joint, Metal/polymer, Semi-constrained (LZJ)
Date received	Feb 27, 1995
Decision date	Jul 31, 1995
Days to decision	154 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Acu Med, Inc.</b>
Location	Beaverton, OR, US
Contact	SHARI L JEFFERS
510(k) history	48 submissions · 39 cleared · 1990-2002

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