

**K980617 MODIFICATION TO REFLEX AEC LINEAR
STAPLER/CUTTER**Apr 9, 1998
76 days to decisionK980617 · Product code: **GDW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k980617/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Implantable (GDW)
Date received	Jan 23, 1998
Decision date	Apr 9, 1998
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Urohealth Systems, Inc.
Location	Costa Mesa, CA, US
Contact	JULIE POWELL
510(k) history	3 submissions · 3 cleared · 1997-1998

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