

K960328  
1 of 1

# R.K. MEDICAL

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## 510(k) SUMMARY

MAR - 4 1996

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92."

Applicant

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Contact

John A. Hutter, Plant Manager  
or  
George R. Krebs (President)

Date

January 23, 1996

Name of Device:

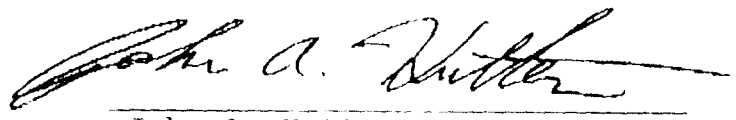
Common or Usual Name: Silk Nonabsorbable Surgical Sutures  
Classification Name: Suture, nonabsorbable, silk

Silk nonabsorbable surgical sutures, USP, manufactured by R. K. Medical L. L. C. are equivalent to silk nonabsorbable surgical sutures manufactured by Davis + Geck.

The silk sutures manufactured by R. K. Medical and D+G can be twisted, or braided, coated with silicone, or wax, or uncoated, dyed black (Logwood) or undyed.

The silk nonabsorbable sutures, USP are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

Testing of suture diameter, suture length, knot pull tensile strength and needle attachment strength according to methods outlined in USP XXIII demonstrates that R. K. Medical silk sutures meet or exceed U. S. P. specifications and are equivalent in terms of the above parameters to silk sutures manufactured by Davis + Geck.



John A. Hutter, Plant Manager