

R.K. MEDICAL

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JUL 29 1996

K 961925

510 (k) SUMMARY

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

Applicant: R.K. Medical L.L.C.
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Contact: Mr. John A. Hutter, Plant Manager
or
Mr. George R. Krebs, President

Date: 5/15/96

Name of Device:

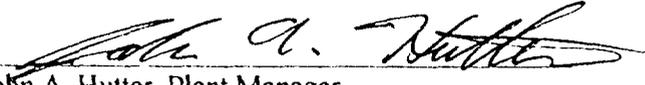
Common or Usual Name: Polyester Nonabsorbable Surgical Sutures
Classification Name: Suture, Nonabsorbable, Synthetic, Polyester

Polyester nonabsorbable surgical sutures USP, manufactured by R.K. Medical, L.L.C. are equivalent to Ti-cron* polyester nonabsorbable surgical suture USP manufactured by Davis & Geck.

The polyester nonabsorbable surgical sutures USP manufactured by R.K. Medical and Davis & Geck are braided and coated with silicone. The R.K. Medical polyester suture is dyed green (D&C Green #6). Davis & Geck's Ti-cron* is dyed blue (D&C Blue #6).

The polyester nonabsorbable surgical 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 described in USP XXIII demonstrates that R.K. Medical Polyester nonabsorbable surgical sutures meet or exceed USP specifications and are equivalent in terms of the above parameters to polyester nonabsorbable surgical sutures manufactured by Davis & Geck.


John A. Hutter, Plant Manager