

R. K. MEDICAL

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MAR - 4 1996

510(k) SUMMARY

"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 R. K. Medical L. L. C.
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Contact John A. Hutter, Plant Manager
or
George R. Krebs (President)

Date January 23, 1996

Name of Device:

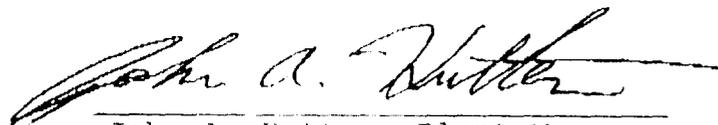
Common or Usual Name: Nylon Nonabsorbable Surgical Sutures
Classification Name: Suture, nonabsorbable, synthetic polyamide

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

The nylon sutures manufactured by R. K. Medical and D+G can be monofilament or braided, coated with silicone, or wax, or uncoated, dyed black or blue or undyed.

The nylon 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 nylon sutures meet or exceed U. S. P. specifications and are equivalent in terms of the above parameters to nylon sutures manufactured by Davis + Geck.


John A. Hutter, Plant Manager