

R.K. MEDICAL

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510 (k) SUMMARY

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

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Contact: Mr. John A. Hutter, Plant Manager
or
Mr. George R. Krebs, President

Date: 5/13/96

Name of Device:

Common or Usual Name: Plain and chromic gut absorbable surgical sutures.

Classification Name: Suture, absorbable, natural

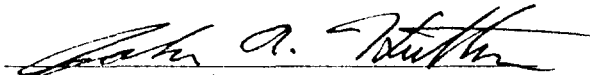
Plain and chromic gut surgical sutures USP manufactured by R.K. Medical, L.L.C. are equivalent to plain and chromic gut surgical sutures manufactured by Davis & Geck. These sutures are absorbable, sterile surgical sutures composed of purified connective tissue (mostly collagen) derived from either the serosal layer of beef (bovine) or the submucosal fibrous layer of sheep (ovine) intestines.

The plain and chromic gut sutures are packaged in packing fluid composed of isopropanol, water, and triethanolamine.

R.K. Medical plain and chromic gut surgical sutures are sterilized by gamma irradiation.

Plain and chromic gut surgical sutures USP are indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular 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 plain and chromic gut surgical sutures meet or exceed USP specifications and are equivalent in terms of the above parameters to plain and chromic gut sutures manufactured by Davis & Geck.


John A. Hutter, Plant Manager