

JUL 10 1986

**SUMMARY OF INFORMATION SUPPORTING
SAFETY AND EFFECTIVENESS:**

As is evident in the submitted information on indications, design, materials, manufacturing, sterilization, packaging and method of use, the Surgical Dynamics™ Pop Rivet** is substantially equivalent to the currently marketed Poly-Medics Lactosorb® Pop Rivet (K951658) and other currently market devices by United States Surgical Corporation.

- Both the Surgical Dynamics™ Pop Rivet** and the Poly-Medics Lactosorb® Pop Rivet (K951658) are indicated for use in soft tissue to bone fixation for reattachment of the glenoid labrum and/or inferior glenohumeral ligament in patients with recurrent anterior dislocation or subluxation of the shoulder.
- Both the Surgical Dynamics™ Pop Rivet** and the Poly-Medics Lactosorb® Pop Rivet (K951658) are comprised of a pin, which widens distally, and a socket, which consists of a cannulated head with circumferential teeth on the underside, as well as four ribbed legs emanating from the underside of the head.
- Both the Surgical Dynamics™ Pop Rivet** and the Poly-Medics Lactosorb® Pop Rivet (K951658) are comprised of biosafe materials.
- Both the Surgical Dynamics™ Pop Rivet** and the Poly-Medics Lactosorb® Pop Rivet (K951658) are intended for arthroscopic procedures for reattachment of soft tissue to bone fixation.
- Both the Surgical Dynamics™ Pop Rivet** and the Poly-Medics Lactosorb® Pop Rivet (K951658) are manufactured in the same facilities, using the same materials and process methods and controls.
- Both the Surgical Dynamics™ Pop Rivet** and the Poly-Medics Lactosorb® Pop Rivet (K951658) are packaged in similar facilities, with the same materials and with the same process methods and controls.
- Both the Surgical Dynamics™ Pop Rivet** and the Poly-Medics Lactosorb® Pop Rivet (K951658) are sterilized in the same facilities, with the same materials and with the same process methods and controls.