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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™ Suture Anchor** is substantially equivalent to the currently marketed Poly-Medics Lactosorb® Suture Anchor (K954443) and other currently market devices by United States Surgical Corporation.

- Both the Surgical Dynamics™ Suture Anchor** and the Poly-Medics Lactosorb® Suture Anchor (K954443) are indicated for attachment of soft tissue to bone in shoulder, wrist and hand procedures

- Both the Surgical Dynamics™ Suture Anchor** and the Poly-Medics Lactosorb® Suture Anchor (K954443) consist of a suture anchor, with polyester suture attached, that is placed into a predrilled bone hole for anchorage of soft tissue.

- Both the Surgical Dynamics™ Suture Anchor** and the Poly-Medics Lactosorb® Suture Anchor (K954443) are comprised of biosafe materials.

- Both the Surgical Dynamics™ Suture Anchor** and the Poly-Medics Lactosorb® Suture Anchor (K954443) are intended for arthroscopic procedures for reattachment of soft tissue to bone fixation.

- Both the Surgical Dynamics™ Suture Anchor** and the Poly-Medics Lactosorb® Suture Anchor (K954443) are manufactured in the same facilities, using the same materials and process methods and controls.

- Both the Surgical Dynamics™ Suture Anchor** and the Poly-Medics Lactosorb® Suture Anchor (K954443) are packaged in similar facilities, with the same materials and with the same process methods and controls.

- Both the Surgical Dynamics™ Suture Anchor** and the Poly-Medics Lactosorb® Suture Anchor (K954443) are sterilized in the same facilities, with the same materials and with the same process methods and controls.

** Trademark name not yet determined.