

K953355

Summary of Safety and Effectiveness

This summary of safety and effectiveness information is being submitted with the requirements of SMDA 1990.

The GIP/Medi-Globe Hot Biopsy Forceps are similar in design, composition (stainless steel and Teflon), and function and performance to the Wilson-Cook GI Hot Biopsy Forceps.

Gastroenterology Urology biopsy through the use of a forceps is an effective, well-known and safe procedure. The GIP/Medi-Globe Hot Biopsy Forceps is designed to be used in conjunction with numerous FDA Approved endoscopes (reference Pentax's FDA registered endoscope K792215 and K792267, Olympus' endoscope K790071).

The 510(k) number for the Wilson Cook Hot Biopsy Forceps is K874314. A detailed list of GIP/Medi-Globe Hot Biopsy Forceps is presented in Exhibit D for comparison. The intended use of the GIP Medi-Globe Hot Biopsy Forceps is identical to the Wilson-Cook device for removal of small polyps in the GI track. The method of operation is the same when used in conjunction with the referenced endoscopes and power supply units.

The cleaning of the GIP/Medi-Globe Hot Biopsy Forceps is identical to the Wilson-Cook Hot Biopsy Forceps. The entire device can be autoclaved or ETO gas sterilized, which are both safe, effective and widely used cleaning methods. The validation protocol for the sterilization of the Hot Biopsy Forceps is included in Exhibit C in the 510 (k) package.

The Hot Biopsy Forceps are shipped assembled and sterile in a peel-open package, similar to the packaging of the Wilson Cook Hot Biopsy Forceps.

Summary data of all of the tests performed on the materials of the Hot Biopsy Forceps were tested for biological reactivity including: Implantation test, Intracutaneous test, and Systemic Injection test. In summary each test meets the requirements for biological reactivity for class VI plastics.

All materials that comprise the Hot Biopsy Forceps are similar in specification and design to the Wilson Cook Hot Biopsy Forceps.

A detailed listing of both GIP/Medi-Globe's and Wilson Cook's Hot biopsy forceps' size and characteristics are included in Exhibits G and H. The working lengths of all of the GIP/Medi-Globe Hot Biopsy Forceps range from 1,200, 1,800, 2,300. The sizes and characteristics of the compared devices are identical with the GIP/Medi-Globe line offering a greater range.

The GIP/Medi-Globe manufacturing facility has been awarded the TÜV Award for Good Manufacturing (GMP) and operates in accordance with ISO

For any questions regarding the GIP/Medi-Globe biopsy forcep, please contact Gina Gallegos at (602)897-2772, 6202 S. Maple Ave, Suite 131, Tempe, AZ 85283 .