Section 5- 510(k) Summary of Safety and Effectiveness

5.1 Statement	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92
5.2 Submitter	ITL Corporation PTY LTD 1/63 Wells Road, Chelsea Heights Victoria, Australian Capital Territory, 3196 Australia **Owner Operator Number**: 9033436
5.3 Company Contact	Susan Finneran Registered Agent, Consultant, ITL Biomedical 186 Old Farm Rd. Abington, MA. 02351 781-664-0074
5.4 Device Name	**Proprietary Name:** Samplok® Segment Sampler **Common Name:** Segment Sampler **Classification Name:** KSS, 864.9050, Blood Bank Supplies
5.5 Predicate Legally Marketed Devices	The Samplok® Segment Sampler, which is the subject of this submission, is substantially equivalent to the previously cleared Hematype Segment Device, BK960083.

5.6 Device Description

The Samplok® Segment Sampler is a single use disposable device that consists of two attached molded polypropylene cylinders with a recessed stainless steel cannula points toward the open end of the each cylinder. To use the sampling device, the user inserts both ends of the segmented tubing into the double-barrel cylinder and attaches a device with a male luer (e.g. syringe) to the female port to extract a measured volume of fluid.

5.7 Device Indications and Intended use

The Samplok® Segment Sampler is used to aid in the extraction of a biological fluid sample from a segmented piece of tubing. Single use only. In vitro diagnostic use only.

5.8 Performance Testing

Performance testing was completed to confirm that Segment Sampler performed as intended and that the design was substantially equivalent to the predicate device. Testing included tube piercing and sample extraction testing, drop test, transportation test, and package integrity test.

TABLE 5.1 TABLE OF SUSTANTIAL EQUIVALENCE

Feature	ITL Segment Sampler	Hematype Segment Device
Regulatory Status	Subject of this submission	Cleared via BK96083
Intended Use/-Indications for Use	To aid extraction of a biological fluid sample from a segmented piece of tubing. Single use only. For *in vitro* diagnostic use only.	For obtaining Blood Samples from Blood Bag Tubing Segments; single use.
Design	Two molded plastic cylinders of similar design. One barrel is the venting cylinder and the other, with a female luer port, is the extraction cylinder. A recessed piercing cannula points toward the open end of each cylinder.	Single molded plastic cylinder with steel cannula inside
Materials	Plastic - polypropylene with stainless steel cannula	Plastic; piercing steel cannula instrument

Functional Characteristics	Both ends of a segment containing fluid are inserted into the double-barrel cylinder. The user attaches a device with male luer e.g. a syringe or vacuum tube to the female luer port to extract a volume of fluid.	The user inserts one end of a tubing segment into the device and squeezes from the other end to discharge the blood sample into the test tube.
Protection Needed for user?	Yes, Universal Precautions to Prevent Exposure to Blood borne Pathogens (gloves, lab coat, safety glasses or equivalent)	Yes, Universal Precautions to Prevent Exposure to Blood borne Pathogens (gloves, lab coat, safety glasses or equivalent)
Energy used or delivered by device?	No	No
Software?	No	No
Rx only?	Yes; for use in laboratory or blood bank; in vitro diagnostic testing accessory	Yes; for use in laboratory or blood bank
Single use only?	Yes	Yes
Sterile	Yes, EtO	No
Patient contact?	No	No