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APPENDIX H

510(k) SUMMARY

This summary is organized per 21 CFR 807.92.

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Name of Contact: Perk Crook

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Name of Device:

Trade Name: Dexterity® Pneumo Sleeve and Protector® Retractor

Common Name: Extended Laparoscopy Device

Classification Name: Extended Laparoscopy Device

Identification of Predicate or Legally Marketed Device(s):

1. Trocar/Cannula by Storz
2. Protector® Retractor by Medical Creative Technologies, Inc.

The Dexterity® Pneumo Sleeve and Protector® Retractor are substantially equivalent to a Trocar/Cannula from an access to the peritoneal cavity standpoint. Both devices allow access to the peritoneal cavity while preventing CO₂ leakage during insertion and withdrawal of instruments. In the case of the Trocar/Cannula, the instruments are laparoscopic instruments and in the case of

the Dexterity® Pneumo Sleeve and Protector® Retractor, the instrument is the surgeon's hand. The Trocar/Cannula protects the wound as does the Protector® Retractor from trauma and/or cross-contamination.

The Protector® Retractor which is a component of this device is the same device as the Protector® Retractor (second predicate device named above) approved by 510(k) Number K954824. The Dexterity® Pneumo Sleeve is made from the same 3 mil thick plastic film used to make the sleeve of the Protector® Retractor.

Description of the Device:

The Dexterity® Pneumo Sleeve is a sterile, disposable device. It prevents leakage of CO₂ and provides an extension of the pneumoperitoneum. It has an adhesive flange at one end that is placed over the incision and adhered to the patient's abdomen. A velcro strap at the other end is used to tighten the Sleeve around the surgeon's arm.

The Protector® Retractor is a sterile, disposable device. The Retractor consists of an open-ended cylinder with a flexible ring at each end. One ring is inserted through the incision into the peritoneal cavity while the other remains outside the incision. The Retractor holds the incision open and protects it against wound contamination.

Statement of Intended Use:

The Dexterity® Pneumo Sleeve is intended to provide abdominal access for the surgeon's hand while preserving pneumoperitoneum during laparoscopic surgery.

The Protector® Retractor is intended to provide incision retraction and to protect it against wound contamination during both laparoscopic and open surgery.

This device allows the surgeon to use his hand while performing corrective surgery in the abdominal cavity under pneumoperitoneum.

Summary of Technical Characteristics of this Device Compared to the Predicate Device:

The Dexterity® Pneumo Sleeve and Protector® Retractor are technically the same as the Trocar/Cannula (one of the predicate devices) in that the Trocar/Cannula

allows access to the abdominal cavity for laparoscopic instruments and the Dexterity® Pneumo Sleeve and Protector® Retractor allow access to the abdominal cavity for the surgeon's hand. The Trocar/Cannula is made out of stainless steel or plastic while the Dexterity® Pneumo Sleeve and Protector® Retractor are made out of a plastic film, flexible plastic and an acrylate adhesive.

The Protector® Retractor component of the Dexterity® Pneumo Sleeve and Protector® Retractor is the "Protector® Retractor" shown as the second predicate device above. The material making up the sleeve of the Protector® Retractor is the same material as used to make the Dexterity® Pneumo Sleeve.

Summary of Performance Data:

Non-clinical Test Results:

Bench testing was performed on each component of the Dexterity® Pneumo Sleeve and Protector® Retractor to assure that they would function as intended during use.

Based on the data collected in the bench testing, it was concluded that all of the materials were proper for their intended use.

Animal Test Results:

Functional testing on pigs:

Several studies were accomplished using pigs to further verify the function of the device and its components. The results of these studies were effective in fine-tuning the design and working out surgeons' preferences.

Clinical Results:

Two clinical studies were conducted with the Dexterity® Pneumo Sleeve. An initial pilot study involving ten surgeons and forty patients validated the operating principles of the device and allowed surgeons to gain additional device experience. As a result of this original study, minor device changes were implemented in the device design.

A second, pivotal clinical study comparing extended laparoscopic surgery using the Dexterity® Pneumo Sleeve and Protector® Retractor with routine laparoscopic surgery for colon resections, was conducted at 10 clinical centers in the United States and Europe. Safety and effectiveness endpoints considered in this trial included: overall procedure time, number of instrument changes required, conversion rates, i.e., the number of times a case could not be completed laparoscopically and had to be converted to an open procedure, direct operation costs, time for patients to return to normal activity, morbidity and mortality. The results of this prospective, randomized, controlled trial confirmed the safety and effectiveness of the Dexterity® Pneumo Sleeve Set for its intended use as an adjunct to laparoscopic surgery.