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SUMMARY OF SAFETY & EFFECTIVENESS INFORMATION

Submitter: InnerDyne, Inc.
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Classification Name: Dilator (Other)
Common/Usual Name: Percutaneous Dilator with Locking Cone
Trade/Proprietary Name: InnerDyne Step Trocar Expandable Port, "Open-*Step*®"

The *Step*® family of products consist of an expandable dilator sheath assembly with an access (Veress-type) needle mounted within its lumen. The tubular member of the dilator sheath is configured so as to be axially compressed to reduce the outside diameter of the device prior to insertion. Upon use, the expanding dilator sheath/needle assembly is inserted through the abdominal/thoracic tissue into the abdominal/thoracic cavity. After insufflation of the cavity, (if deemed necessary), the access needle is removed. The dilator cannula assembly, which consists of a blunt obturator, dilation cannula, and a pneumo valve, is inserted through the lumen of the dilator sheath which expands radially to accommodate it. This process in turn, radially expands the walls of the surrounding tissue. Following dilation the obturator is removed, leaving the expanding dilation sheath and dilator cannula in place to provide a sealed port for passage of diagnostic and surgical instruments.

The subject Open-*Step*® system configuration allows the user to access the desired region through open laparoscopic surgical techniques for passage of small diagnostic instruments accomplished without a radially expanding sheath. An incision is made at the target insertion site using standard technique. The surgeon places a finger into the previously created incision to ensure that a free cavity has been entered. The Open-*Step*® access device is inserted into the incision with the adjustable cone secured against the bottom of the cannula/dilator. The adjustable cone is slid down the cannula assembly and into the incision, helping to form an adequate seal. Position the desired cannula depth into the cavity by advancing or retracting the cannula assembly. The dilator cannula can then be removed from the lumen of the cannula while leaving the cannula inserted through the tissues creating an access/passage route for operative instruments.

The device is assembled from medical grade materials under GMP and ISO conditions. Components are molded and machined by qualified suppliers. The components are

assembled and secured by adhesives, welds, and mechanical interlocks.

The subject InnerDyne, Inc., Open-*Step*® device is substantially equivalent to the predicate InnerDyne, Inc., *Step*® devices (K943253, K940232, K950632, and K950658), as well as the Ethicon, ENDOPATH, Blunt-Tip Disposable Surgical Trocar, the United States Surgical Corporation, BLUNTPORT, Disposable VERSAPORT Trocar System for Open Laparoscopy, the Hasson Stable Access Cannula (SAC) of Marlow Surgical Technologies, Inc., the Core Dynamics Entree Blunt Tip Trocar & Adaptor (K932020), and the Linvatec Hasson Open Laparoscopy Cannula (K942447). The subject Open-*Step*® device is similar to the referenced predicates in size, function, product dimensions and general indications for use.

The *Step*® family of products are intended for use during minimally invasive surgery for temporary dilation access to the abdominal and thoracic cavities for passage of diagnostic and operative instruments into the abdominal and thoracic cavities. The device is configured to be used as either a primary or secondary stick. The subject Open-*Step*® device is configured to be used with the open laparoscopic surgical approach.

The basic design principles for the subject InnerDyne, Inc., Open-*Step*® device and the predicate *Step*® devices (K943253, K940232, K950632, and K950658) are similar, and remain essentially unchanged from information previously provided to the Agency. The product configuration, composition, and utilized materials are similar in each of the products. The principles of operation for the InnerDyne, Inc., Open-*Step*® device, and the predicate *Step*® devices (K943253, K940232, K950632, and K950658) are similar. That is, each of these products employs a similar insertion technique, indications for use, contraindications for use, warnings and precautions. Additionally, the Open-*Step*® device is substantially equivalent to the aforementioned competitive predicates in basic principles of operation as well. The subject device differs from the referenced *Step*® predicates only through elimination of the reducer cap, expandable sleeve, access needle, presentation style of the product, and adoption of a locking adjustable cone which is attached to the cannula barrel.

From the foregoing, we conclude that the Open-*Step*® device is as safe and effective as currently marketed devices for the stated indications.