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## SUMMARY OF SAFETY & EFFECTIVENESS INFORMATION

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Classification Name: Dilator (Other)
Common/Usual Name: Percutaneous Dilator With Sheath
Trade/Proprietary Name: InnerDyne Step Trocar Expandable Port, "Mini*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.

This system configuration allows the user to initially place a small diameter dilator cannula for passage of small diagnostic instruments. The dilator cannula can then be removed from the lumen of the dilator sheath while leaving the sheath inserted through the tissues. A larger diameter dilation cannula can then be inserted through the dilator sheath to create a larger port for passage of the larger 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., Mini*Step*® device is substantially equivalent to the predicate InnerDyne, Inc., *Step*® devices (K943253, K940232, K950632, and K950658), the Imagyn Microlap Introducer, K943810, and the USSC AutoSuture MiniSite Introducer. The subject Mini*Step*® device is similar to the referenced predicates in size, function, product dimensions and 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 basic design principles for the subject InnerDyne, Inc., Mini*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. In comparative terms of working channel diameter, the subject Mini*Step*® device is substantially equivalent to the Imagyn and USSC predicates as well. The principles of operation for the InnerDyne, Inc., Mini*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. The subject device differs from the referenced *Step*® predicates only in consideration of lowering the working diameter range down to 2mm from the previously cleared 5mm size.

The *Step*® device design has been widely tested in porcine models to provide the access for instruments employed in surgical procedures; laparoscopic cholecystectomy has been used as typical. Since the device incorporates a Veress-type needle for access, both the primary and secondary sticks have been made without difficulty. The radial expansion achieved during dilation of product sizes provides effective anchoring within the tissue throughout the procedure.

The residual tissue defects from the use of the *Step*® devices and the defects left by standard surgical trocars have been studied by Drs. Bhoyrul, Mori, and Way at the University of California, San Francisco. They have observed that the Step® device leaves significantly smaller defects than conventional trocars with reduced tissue ecchymosis. They also conclude that the use of *Step*® should reduce the risk of trocar related complications. Additional clinical overviews have been published within the literature by other users outlining their experience with *Step*® products.

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