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**510(k) Summary**

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Device: Imagyn Expandable Laparoscopic Introducer

Predicate Devices: Imagyn MicroLap Introducer  
Innerdyne, Inc. Step Trocar Expandable Port

Device Description: The Imagyn Expandable Laparoscopic Introducer is a single use, sterile device made from both metal and plastic components. For second-site use during laparoscopic procedures, the device incorporates a valve system that maintains adequate insufflation pressures while diagnostic or operative instruments are in use.

Intended Use of Device: The Imagyn Expandable Laparoscopic Introducer is indicated for use in providing access to the peritoneal cavity for diagnostic and operative instruments during laparoscopic procedures.

Technological Comparisons: The device has equivalent technological characteristics to the predicate devices to achieve laparoscope and/or laparoscopic instrument insertion without loss of pneumoperitoneum.

Performance Summary: Non-clinical tests were performed to demonstrate that the device performed according to its description and intended use. These included visual, dimensional, leak, puncture, instrument passage, and mechanical testing and demonstrated adequate performance for the intended use.