OCT 7 1998

K982417

SUMMARY OF SAFETY & EFFECTIVENESS INFORMATION

Submitter: InnerDyne, Inc.
5060 West Amelia Earhart Drive
Salt Lake City, Utah 84116
(801) 350-3600

Date Prepared: 10 July 1998

Contact: Rick Gaykowski
Corporate Vice President, Regulatory Affairs
and Quality Assurance

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

The Step Trocar Expandable Port *Step*® device consists 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 target cavity or hollow organ.

For laparoscopic access to the abdominal/thoracic cavities, the following instructions should be utilized. 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, therapeutic, and/or surgical instruments.

For access to hollow body organs (e.g., intragastric placement viewed as typical), the following instructions should be utilized. If endoscopic technique is utilized, an endoscope is advanced into the stomach using standard techniques, followed by stomach insufflation. An abdominal incision is made and the access needle/sheath assembly is inserted directly through the abdominal and stomach walls into the stomach. The access needle is removed and the cannula/dilator is advanced through the radially expanding sleeve. If laparoscopic technique is utilized, under laparoscopic vision the abdominal cavity is entered and the stomach site is selected for insertion of the access device. The sheath/needle assembly, is advanced into the stomach. The access needle is removed, leaving the expandable sheath in place. The dilator cannula assembly is inserted through the lumen of the dilator sheath which expands radially to

accommodate it. Following dilation the dilator is removed, leaving the expandable sheath and dilator cannula in place to provide a sealed port for passage of the selected instruments. Once the desired instruments are placed, the access device cannula and expanding sheath are removed, allowing the stomach and abdominal wall to contract/relax. **(Access to hollow organs other than the stomach, can be achieved following general laparoscopic technique and the access methodology described above.)**

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 conditions. Components are molded and machined by qualified suppliers. The components are assembled and secured by adhesives, welds, and mechanical interlocks. The *Step*® radially expanding access device is available in various lengths and working diameters to accommodate the selected size of indicated medical instruments. The subject product shall be available in both disposable and reusable forms.

The subject InnerDyne, Inc., Step Trocar Expandable Port, *Step*® device is substantially equivalent to the predicate InnerDyne, Inc., *Step*® device versions in basic design, product configuration, composition, utilized materials, function, deployment, warnings and precautions, contraindications, and intended use for access to abdominal/thoracic cavities, and equivalent to the InnerDyne, Inc., *R.E.D.*® device versions for access to hollow body organs.

The subject *Step*® device is intended for use during minimally invasive surgery for temporary dilation access to the abdominal and thoracic cavities for passage of diagnostic, therapeutic and operative instruments into the abdominal and thoracic cavities, and for percutaneous access to hollow body organs with typical use in such procedures as percutaneous gastrostomy, percutaneous enterostomy, percutaneous cystostomy, percutaneous cholecystostomy, and dilation of biliary and urethral strictures. The device is configured to be used as either a primary or secondary stick.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 1998

Mr. Rick Gaykowski
Corporate Vice President, Regulatory Affairs
and Quality Assurance
InnerDyne, Inc.
5060 West Amelia Earhart Drive
Salt Lake City, Utah 84116

Re: K982417
Trade Name: Innerdyne Step Trocar Expandable Port, "STEP®"
Regulatory Class: II
Product Code: GCJ
Dated: July 10, 1998
Received: July 13, 1998

Dear Mr. Gaykowski:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (~~if known~~): K982417

Device Name: InnerDyne, Inc., Step Trocar Expandable Port, *Step*™

Indications for Use: The InnerDyne, Inc., *Step*® device is intended to provide dilation access for the performance of laparoscopic procedures to establish a port of entry for diagnostic, therapeutic, and operative procedures.

- Laparoscopic access to the abdominal region, both primary and secondary punctures;
- Thoracoscopic access to the thoracic cavity, both primary and secondary punctures; and
- Percutaneous access into hollow body organs with typical use in such procedures as percutaneous gastrostomy, percutaneous enterostomy, percutaneous cystostomy, percutaneous cholecystostomy, and dilation of biliary and urethral strictures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982417

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)