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SUMMARY OF SAFETY & EFFECTIVENESS INFORMATION

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

Date Prepared: 12 March 1999

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

Classification Name: Dilator (Other)
Common/Usual Name: Percutaneous Dilator w/ Sheath
Trade/Proprietary Name: InnerDyne , Radially Expanding Dilation "*RED*® " Device

The *RED*® device is an expandable dilator sheath assembly, consisting of a radially expanding sleeve, inflation syringe, cannula (with integral valve system), dilator, and insertion instrument (either an access needle or guidewire). The tubular member of the expandable sleeve is configured so as to be radially compressed to reduce the outside diameter of the device prior to insertion. Upon use, the dilator assembly is inserted through the radially expandable sleeve, penetrating the tissue into the target cavity (e.g., abdominal/peritoneal) or hollow organ.

For access to target cavities and hollow organs, the following instructions should be utilized. The needle and radially expanding sleeve should first be inserted into the target location. The needle removed, leaving the radially expanding sleeve in place. The dilator cannula assembly, which consists of a blunt dilator and dilation cannula, is then inserted through the lumen of the expandable sleeve which expands radially to accommodate it. This process in turn, radially expands the walls of the surrounding tissue. Following dilation the dilator is removed, leaving the radially expanding dilation sleeve and dilator cannula in place. This technique allows the user to benefit from the unique safety features and controllability of radial dilation by going from a less traumatic initial stick, followed by radial dilation to the desire working channel.

Fill the provided syringe with 2.0 cc of liquid (A 50% concentration is recommended if using contrast). Attach the syringe to the reflux valve and draw a small vacuum to aspirate air. Tilt the syringe so that the air bubble floats away from the reflux valve. Inflate the balloon and remove the syringe. Once the working channel is established, the dilator be removed from the cannula leaving the working cannula in place to provide a sealed port for passage of diagnostic, therapeutic, and/or 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 radially expanding sleeve while leaving the sleeve inserted through the tissues. A larger diameter dilation cannula can then be inserted through the expanding sleeve 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 *RED®* device is available in various lengths and working diameters to accommodate the selected size of indicated medical instruments. The subject product may be supplied in both disposable and reusable forms.

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

The subject *RED®* device is intended for use during minimally invasive surgery for temporary dilation access to the abdominal/peritoneal 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. The device is configured to be used as either a primary or secondary stick.

From the foregoing, we conclude that the subject *RED®* 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

AUG -2 1999

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

Re: K990854
InnerDyne, Inc., Radially Expanding Dilation,
RED®, Device
Dated: June 14, 1999
Received: June 16, 1999
Regulatory Class: II
21 CFR §876.5010/Procode: 78 FGE
21 CFR §876.5090/Procode: 78 FFA
21 CFR §876.5980/Procode: 78 KGC
21 CFR §876.1500/Procode: 78 GCJ

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 legally marketed predicate 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 requirements, 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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**510(k) Number (if known):** K990854

**Device Name:** InnerDyne, Inc., Radially Expanding Dilation, *RED®*, Device.

**Indications for Use:** The InnerDyne, Inc., *RED®* device is intended for use during minimally invasive surgery to provide temporary dilation access to the abdominal/peritoneal cavity and to the lumen of specified internal organs to establish a port of entry for diagnostic, therapeutic, and operative instruments. Typical procedures for product use include:

- Laparoscopic access to the abdominal/peritoneal cavity;
- Percutaneous gastrostomy;
- Percutaneous enterostomy;
- Percutaneous cystostomy;
- Percutaneous cholescystostomy; 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)

David A. Kessler

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990854

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

(Optional Format 1-2-96)