

K973916

510(K) SUMMARY

MAR - 9 1998

1. SUBMITTER:

NP Medical, Inc.
101 Union Street
Clinton, MA 01510
Telephone: 978-365-2500

Contact: Mike Jones, Quality Assurance Manager
Date Prepared: October 9, 1997

2. DEVICE:

Classification Name: Set, Administration, Intravascular
Trade Name: NP Medical Capless Luer Activated Valve
Class II per 21 CFR 880.5440
The Product Code is 80FPA

3. PREDICATE DEVICE:

The predicate device used to determine substantial equivalence for the NP Medical **Capless Needleless Luer Connector** is the ICU Medical Clave Needleless Connector (K915571 / K941190).

4. DEVICE DESCRIPTION:

The Capless Luer Activated Valve is a two-part device consisting of a **Gland Housing Assembly** and a **Gland/Center Post Assembly**, as described below:

The **Gland** is a valve/gasket which provides a seal against the syringe/luer connector when the device is being utilized. The Gland incorporates a slit to accept the syringe/luer connector. The Gland is also the swabbable surface of the Capless Luer Activated Valve. The valve can be easily swabbed per hospital protocol before each connection.

The **Center Post** mechanically supports the Gland and serves as the primary high pressure seal to keep the fluid path closed during the resting state.

The Gland and the Center Post are mechanically press-fit together to form the **Gland/Center Post Assembly**.

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In the resting state, the Center Post is flush with the walls of the Gland Housing, ensuring that there is no fluid path. As the device is activated by a syringe/male luer connector, the flexible Gland is forced open and the Center Post is pushed down. As the Center Post is forced further down into the Gland Housing, the fluid path is established.

5. INTENDED USE:

The Capless Luer Activated Valve, incorporating a luer activated valve, is intended for use in facilitating needleless fluid delivery and may be swabbed with antiseptic just prior to use, thereby eliminating the need for capping between uses.

6. COMPARISON OF CHARACTERISTICS:

The Capless Luer Activated Valve and the currently marketed Clave Needleless Connector are very similar in design: Both devices consist of a silicone valve encapsulated within a plastic housing. Both devices have the same Intended Use.

7. PERFORMANCE DATA:

The following performance data was provided in support of the substantial equivalence determination:

1. Mechanical Testing:

Mechanical Testing has been conducted on the Capless Luer Activated Valve to demonstrate that the device's performance characteristics are adequate for the intended use.

The results of the Mechanical Testing demonstrate that the NP Medical Capless Luer Activated Valves meet their performance requirements.

2. Biocompatibility Testing:

Full biocompatibility testing has been performed on the materials being proposed in this 510(k) submission, per ISO 10993. The materials passed all of the biocompatibility tests.

3. Microbial Challenge Testing:

Microbial Challenge testing has been conducted on the Capless Luer Activated Valve. The results of the testing demonstrate that, in response to excessive microbial challenge conditions, the sterility of the fluid pathway was maintained.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 9 1998

Mr. Paul A. Caracciolo
Quality Assurance Manager
N.P. Medical Incorporated
101 Union Street
Clinton, Maryland 01510

Re: K973916
Trade Name: NP Medical Capless Luer Activated Valve
Regulatory Class: II
Product Code: FPA
Dated: January 23, 1998
Received: January 28, 1998

Dear Mr. Caracciolo:

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

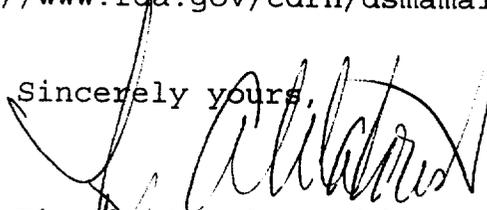
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4618. 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,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K973916

INDICATIONS FOR USE STATEMENT

The Capless Luer Activated Valve, incorporating a luer activated valve, is intended for use in facilitating needleless fluid delivery and may be swabbed with antiseptic just prior to use, thereby eliminating the need for capping between uses.

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

Concurrence of GDRH, Office of Device Evaluation (ODE)

Patricia Curran

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K973916

Prescription Use

OR

Over-The-Counter Use

(Optional Format 1-2-96)