

K964439

JUL 16 1997

510 K SUMMARY
Prepared: November 4, 1996

1. Submitted by:

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V. P. RA/QA
BMW Medical, Inc.
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Tel: (801) 954-8444
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2. Contact Person

Roger L. Richins
V. P. RA/QA

3. Device Identification:

Trade Name:	to be determined
Common Name:	Needlefree Valved Connector and Cap
Classification Name:	Intravascular Catheter Accessory

4. Predicate Device(s): BMW Medical, Inc's Clampless Valved Catheter and B. Braun's Safsite.

5. Device Description: BMW's Needlefree Valved Connector is a rigid plastic adapter with a male luer port on the distal end for attachment to I.V. access systems (e.g., catheters). The proximal end terminates in a female luer lock fitting which may be attached to any I.V. administration set terminating in a standard male luer. The female luer is capped when not in use to minimize the potential for contamination.

The plastic adapter houses a slitted disc of silicone rubber which serves as a three-way valve. The valve is normally closed when it is not in use. The valve opens towards the I.V. access system when fluids are infused into the patient and it opens away from the I.V. access system to permit aspiration of blood samples. The valve is captured (sandwiched) between the seating surfaces of the two-piece adapter. The seating surfaces of the adapter are held in position by a bond between the proximal and distal pieces of the adapter. The connector valve is packaged in a sterile blister pack with male luer cap(s). The caps will also be packaged and sold individually.

6. **Intended Use:** The BMW Needlefree Valved Connector is designed for needlefree access to IV infusion systems for injection of fluids or aspiration of blood samples.

7. **Summary of Technological Characteristics of Device in relation to Predicate Device(s):**

A. **Comparison of Physical Characteristics:**

The physical characteristics of BMW's Needlefree Valved Connector are substantially equivalent to those of the hub of BMW's Clampless Valved Catheter except for the attachment mechanisms. The Needlefree Valved Connector has a male luer lock on the distal end of the adapter, permitting its direct, or indirect, attachment to a venous access system (catheter). The predicate device has a tapered barbed extension on the distal end of its plastic adapter which mechanically locks into and is integrally attached to BMW's Clampless Valved Catheter. The male luer lock attachment of the Needle Free Connector meets ANSI standards and poses no new questions of safety and efficacy to the user.

B. **Comparison of Performance Characteristics:**

The Needlefree Valved Connector performs exactly the same as the hub of BMW's predicate device. The 2-piece adapters of both devices house a slitted disc of silicone rubber which serves as a three-way valve. The valve remains closed when the device is not in use. The valve opens toward the distal end of the I.V. administration system (catheter) when fluids are infused through it, and it opens away from the I.V. device to permit aspiration of blood samples. BMW's new connector offers the same needlefree access features as Braun's Safsite. Both reduce the risk of an accidental stick with a blood-contaminated needle. Both must be capped when not in use to minimize the potential for contamination.

8. **Conclusion:**

BMW's Needlefree Connector and Cap are substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Roger L. Richins
Vice President Regulatory Affairs & Quality Assurance
BMW Medical, Incorporated
3598 West 1820 South
Salt Lake City, Utah 84104-4959

JUL 16 1997

Re: K964439
Trade Name: Needle-Free Valved Connector And Cap
Regulatory Class: II
Product Code: FPA
Dated: June 26, 1997
Received: June 30, 1997

Dear Mr. Richins:

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 (Pre-market 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 pre-market notification submission does not affect any obligation you might have under sections 531

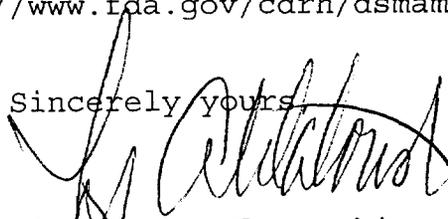
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

K964439

510(k) Number (If known): _____

Device Name: Needlefree Valved Connector and Cap

Indications For Use:

The BMW Needlefree Valved Connector is designed for needlefree access to IV infusion systems for injection of fluids or aspiration of blood samples.

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

Concurrence of CDRH, Office of Evaluation (ODE)

(Division Sign-Off) Palma Cuervo
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K964439

Prescription Use

OR

Over-The-Counter-Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)