

SEP 10 1999

10992015

ATTACHMENT G

SUMMARY of SAFETY and EFFECTIVENESS for the DIB-RA INFUSOR

I. Standards and Intended Use

The Freedom™ Infusion System pump will conform to the AMMI Draft Infusion Device Standard. The intended use of the Freedom™ Infusion System is identical to the legally marketed PainBuster system.

II. Manufacturing and Testing Procedures

All manufacturing operations are performed in a class 10,000 clean room in accordance with GMP regulations. The silicone balloons are 100% tested to an internal pressure of 110 ± 5 mmhg. Normal clinical operating pressure has been measured at approximately 70 mmhg. Full traceability of production lots will be maintained.

III. Prior In-Vitro Tests and Clinical Experience

A) Performance data and test protocols for burst testing of the DIB infusors are included as FDA file no's. K930404, K941766, and K955849. Bench test protocols and study results for flow rate, flow profile, and accuracy are also reported in the above referenced FDA filings

B) Clinical Experience: legally marketed DIB pumps have been used clinically in the USA for obstetrical analgesia, post operative pain, chronic pain and intravenous infusions. (See attached *Anesthesiology News*)

IV. **Contact Address:** Inquiries related to the Freedom™ Infusion System should be directed to:

NOVACON Corporation
5451 Hilltop Avenue
Lake Elmo, MN 55042-9539
Tel: (651) 704-9160
Fax: (651) 704-9161



SEP 10 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. David P. Lang
NOVACON Corporation
5451 Hilltop Avenue North
Lake Elmo, Minnesota 55042-9539

Re: K992015
Trade Name: Freedom™ Infusion System
Regulatory Class: II
Product Code: MEB
Dated: June 11, 1999
Received: June 15, 1999

Dear Mr. Lang:

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:

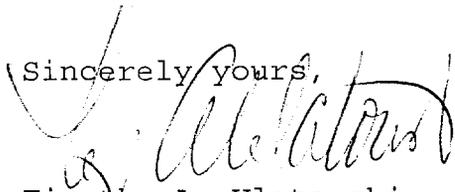
Page 2 - Mr. Lang

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) 594-4692. 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" (21CFR 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,


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

Enclosure

ATTACHMENT A

Page _____ of _____

510(k) Number (if known): _____

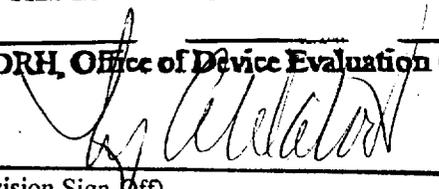
Device Name: Freedom™ Infusion System

Indications For Use:

- 1) Freedom™ is intended to provide continuous infusion of a local anesthetic directly into the intraoperative site for postoperative pain management.
- 2) Freedom™ is intended to deliver pain medication percutaneously via a catheter attached to the pump.
- 3) Freedom™ is a single use only device.
- 4) Freedom™ is intended for use as an ambulatory device and is intended for, but limited to, use in the home environment.
- 5) Freedom™ is not intended for epidural, subcutaneous, or vascular drug delivery.
- 6) Freedom™ is not intended for use with chemotherapy drugs.
- 7) Freedom™ is not intended for use with blood, blood products, or TPN.

(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 Dental, Infection Control,
 and General Hospital Devices

510(k) Number K992015

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)