K021996
p.1/1

AUG 23 2002

BOLTON MEDICAL

510(k) Summary of Safety & Effectiveness

This 510(k) Summary of Safety and Effectiveness for the Bolton PTA Catheter System is provided as required per Section 513(I)(3) of the Food, Drug and Cosmetic Act.

1. **Submitter:** Bolton Medical, Inc.
16-00 Pollitt Drive
Fair Lawn, NJ 07410

Contact Person: Vivian Kelly
Tele: (201) 797-0014
Fax: (201) 797-0201

Date prepared: August 20, 2002

2. **Proprietary Name:** Bolton PTA Catheter
Common Name: Peripheral Transluminal Angioplasty Catheter
Classification Name: Percutaneous Catheter (21 CFR 870.1250)

3. **Predicate or legally marketed devices that are substantially equivalent:**
   - Smash™ PTA Catheter, Schneider (USA) Inc. (K972512)
   - NuMED Ghost II PTA Catheter, NuMED, Inc. (K003972)
   - PTA Balloon Catheter, Cook Incorporated (K001087)
   - RX VIATRAC 14 Peripheral Dilalation Catheter, Guidant Corporation (K000101)
   - Finch and Copperhead PTA Catheters, Mallinckrodt, Inc. (K983830)
   - Opti-plast® Centurion 5.5 PTA Catheter, C.R. Bard, Inc. (K973012)

4. **Description of the device:**
The Bolton PTA Catheter is a single use, dual lumen, percutaneous, angioplasty catheter with a distally mounted semi-compliant balloon for the dilatation of narrowed peripheral vessels. The dual lumen consists of a balloon lumen and a guidewire lumen with two radiopaque to aid in balloon positioning. The catheter is packaged sterile and is nonpyrogenic.

5. **Intended Use:**
The Bolton PTA Catheter is indicated for percutaneous transluminal angioplasty of narrowed or obstructed peripheral arteries such as the iliac, femoral, iliofemoral, renal, popliteal, tibial, tibioperoneal, infrapopliteal, peroneal, and profunda vessels and for treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is not intended for use in the coronary arteries.

7. **Comparison of the technological characteristics of the device to predicate devices:**
The Bolton PTA Catheter is substantially equivalent to the above reference predicate devices. There are no significant differences between the Bolton PTA Catheter and other PTA catheters currently being marketed which would adversely affect the use of the Bolton PTA Catheter. It is substantially equivalent to these other devices in design, function, material and intended use.

8. **Summary of Non-Clinical Testing**
Bench testing was conducted using the *Guidance for the Submission of Research and Marketing Application for Interventional Cardiology Devices* (5/1994) as a guide. Biocompatibility testing was based on ISO 10993-1 and the FDA Blue Book Memorandum #G95-1. The results of the bench and biocompatibility tests demonstrate that the Bolton PTA catheter is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 23 2002

Bolton Medical, Inc.
c/o Ms. Vivian Kelly
Regulatory Affairs Manager
16-00 Pollitt Drive
Fair Lawn, NJ 07410

Re: K021996
Trade Name: Bolton PTA Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: LIT and DQY
Dated: June 17, 2002
Received: June 18, 2002

Dear Ms. Kelly:

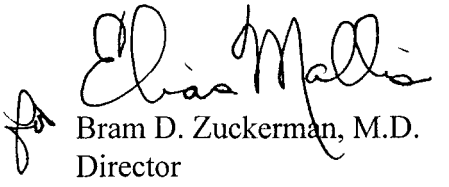
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

BOLTON MEDICAL

Bolton Medical Group
A Cardinal Health Company

Indications for Use Statement

510(k)Number (if known) K021996

Device Name **BOLTON PTA CATHETER**

Indications for Use

The Bolton PTA Catheter is indicated for percutaneous transluminal angioplasty of narrowed or obstructed peripheral arteries such as the iliac, femoral, iliofemoral, renal, popliteal, tibial, tibioperoneal, infrapopliteal, peroneal, and profunda vessels and for treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is not intended for use in the coronary arteries.

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 Cardiovascular
and Respiratory Devices

510(k) Number K021996

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)