K971402

APR 15 1998

510(k) SUMMARY INFORMATION

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

A. Submitter's Information:

Submitter's Name:	Bard Diagnostic Sciences, Inc.
Address:	12277 134th Ct., NE
Contact Person:	Glen Paul Freiberg
Contact Person's Phone:	(206) 814-1520
Contact Person's Fax:	(206) 814-1521
Date of Preparation:	April 10, 1997

B. Device Name:

Trade Name:	Bard® BTA TRAK™ Test
Common / Usual Name:	BTA TRAK™ Test
Classification Name:	Tumor Associated Antigen Immunological Test System

C. Predicate Device Name:

Trade Name:	Bard® BTA® Test P940018 - Reclassified to Class II Bard® BTA *stat*™ Test K964151

Bard Diagnostic Sciences, Inc., claims substantial equivalence to the above mentioned tests.

D. Device Description: The BTA TRAK test for bladder tumor associated antigen is an enzyme immunoassay utilizing monoclonal antibodies to specifically detect the presence of bladder tumor associated antigen in urine.

E. Intended Use:

The BTA *stat* test is for the quantitative detection of bladder tumor associated antigen in human urine.

F. Indications for Use:

The BTA TRAK test is an *in vitro* diagnostic assay indicated for the quantitative detection of bladder tumor associated antigen in human urine. This test is intended for use as an aid in management of bladder cancer patients in conjuction with cystoscopy.

G. Substantial Equivalence & Technological Characteristics Summary:

The Bard BTA TRAK test and the Bard BTA *stat* test both use the same monoclonal antibody pair to detect bladder tumor associated antigen. The BARD BTA TRAK test is an enzyme immunoassay in microtiter plate format. The Bard BTA *stat* test is a lateral flow assay which detects antigen though antigen-specific antibodies. The Bard BTA Test is a test strip assay which detects "bladder tumor associated analytes" through an agglutination interaction with IgG coated latex particles. All of the assays are intended for management of bladder cancer patients. The first two detect a different substance than the original BARD BTA test.

Specificity Results of the Bard BTA TRAK test by Disease State

Category	N	Mean - U/mL
Healthy Subjects	212	4.1
Male > 50 years	21	2.7
Female > 50 years	67	93
M/F 35 - 50 years	164	4.5
Non-Genitourinary (GU) Benign Diseases	52	2.0
Genitourinary Diseases		
BPH	26	9.0
Benign Renal Disease	32	78.7
Misc. GU Disease	94	26.3
UTI/Cystitis	30	61.8
STD	24	11.2
Other	40	8.8
Genitourinary Trauma	54	1031.9
Genitourinary Cancers		
Prostate Cancer	45	64.4
Renal Cancer	7	1039.0
Other Cancers	25	3.3
Active Bladder Cancer [A]		
Grade I	53	212.4
Grade II	56	543.0
Grade III	96	913.9
Stage Tis	18	68.4
Stage Ta	108	316.7
Stage T1	38	851.0
Stage T2 - T4	50	1250.5
No Evidence of Disease [B]	107	31.8

A - Includes 2 patients with grade but unknown stage and 11 with stage but unknown grade

B - History of bladder cancer but no disease evident on follow-up with cystoscopy and/or biopsy.

H. Performance Data:

The BTA TRAK test sensitivity results were determined using urine samples from 220 patients with biopsy proven bladder tumors. Samples were collected from diverse geographic locations and stored frozen until tested. Testing of samples for this study was performed on-site at Bard Diagnostic Sciences, Inc. The average age was 68 years and 79% were males. Results are presented below by stage and by grade of the tumor.

BTA *stat* Test Sensitivity by Stage and Grade*

Stage	**N**	**Sensitivity (%)**
Ta	108	59
T1	38	92
≥T2	50	88
Tis	18	67
Grade	**N**	**Sensitivity (%)**
1	53	53
2	56	68
3	96	72
Overall	216	72

* Includes 2 patients without stage and 11 without grade determinations.

In conclusion, the Bard BTA TRAK Test is substantially equivalent to the predicate devices referenced in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 15 1998

Ms. Alicia J. Moffat
Regulatory, Regulatory Affairs Specialist
Bard Diagnostic Sciences, Inc.
12277 134th Ct. N.E., #100
Redmond, Washington 98052

Re: K971402/S3
Trade Name: Bard® BTA TRAK™ Test
Regulatory Class: II
Product Code: MMW
Dated: February 19, 1998
Received: February 20, 1998

Dear Ms. Moffat:

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

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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) 594-4588. 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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html"

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION I D
INDICATIONS FOR USE

510(k) Number (if known): K971402

Device Name: Bard® BTA TRAK™ Test

Indications for Use:

The Bard BTA TRAK Test is indicated for the quantitative detection of bladder tumor associated antigen in urine of persons diagnosed with bladder cancer. This test an aid in the management of bladder cancer patients in conjunction with cystoscopy.

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

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

(Optional Format 1/2/96)

Peter E Martin

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number _____