MAR 2 8 2002

K013984

510 (k) Summary of
Safety and Effectiveness
IMMULITE® and IMMULITE® 2000 BR-MA

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

Name: Address:	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, California 90045
Telephone Number:	(310) 645-8200
Contact Person:	Edward M. Levine, Ph.D.
Date of Preparation:	March 22, 2002
Catalog Number:	LKBR1, LKBR5 (100, 500 tests) L2KBR2 (200 tests)
Device Name Trade:	IMMULITE® BR-MA and IMMULITE® 2000 BR-MA
Common:	Reagent system for the determination of CA15-3 antigen in serum.
Classification:	MOI, Class II device
Manufacturer of IMMULITE BR-MA:	Euro/DPC Limited Glyn Rhonwy Llanberis, Gwynedd LL55 4EL United Kingdom (Manufactured under a Quality System-ISO9002/ISO13488/EN46002)
Sole U. S. Importer of IMMULITE BR-MA:	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, CA 90045-5597
Manufacturer of IMMULITE 2000 BR-MA:	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, CA 90045-5597 (Manufactured under a Quality System-ISO9001/21CFR,Part 820/EN46001)

Establishment Registration #: Euro/DPC – Not applicable
DPC Registration number is 2017183

Substantially Equivalent
Predicate Devices: Bayer Immuno 1™ CA 15-3™ (K964703)
Chiron ACS 180 BR (CA27.29)

Description of Device:

IMMULITE BR-MA and IMMULITE 2000 BR-MA are clinical use devices intended for use with their respective IMMULITE and IMMULITE 2000 Automated Immunoassay Analyzers for the quantitative measurement of CA15-3 antigen in serum.

Intended Use of the Device:

IMMULITE BR-MA and IMMULITE 2000 BR-MA are clinical use devices intended for in vitro diagnostic use with IMMULITE analyzer – for the quantitative measurement of CA 15-3 antigen in human serum, as an aid in the detection of recurrence in previously treated stage II and stage III breast cancer patients, and in the management of metastatic breast cancer patients by monitoring disease progression or response to treatment. Serial testing for patient CA 15-3 values should be used in conjunction with other clinical methods used for detecting early recurrence in Stage II and stage IIII disease and for monitoring response to treatment in patients with metastatic breast cancer.

Summary and Explanation of the Test:

CA 15-3 is a high molecular weight (300 to 450 kDa) polymorphic epithelial mucin. The heterogeneous breast cancer associated mucins consist of a repeated polypeptide core sequence and an outer shell of carbohydrate. Serum CA 15-3 values increase with clinical stage of breast cancer, the highest values occurring in metastatic disease. Serial determinations of CA 15-3 are most useful as an indicator of response to therapy. The measurement of CA 15-3 antigen is more sensitive and specific than the determination of carcinoembryonic antigen (CEA), having a lower percentage positivity with benign breast lesions, liver cirrhosis and other carcinomas – 99.9% of serum donated by healthy volunteers contained less than 40 U/mL of CA 15-3. CA 15-3 is not elevated during pregnancy. The percentage of raised values found in breast cancer can be as high as 98%, but this depends primarily on the tumor stage of the patient population studied. Elevated levels have also been found in patients with lung cancer (63%) and ovarian cancer (80%).

IMMULITE BR-MA and IMMULITE 2000 BR-MA are two-step sequential chemiluminescent enzyme immunoassays, based on ligand-labeled monoclonal antibody and separation by anti-ligand-coated solid phase.

Performance Equivalence - Technology Comparison:

IMMULITE BR-MA is a chemiluminescent enzyme immunoassay and Immuno 1 CA 15-3 is a magnetic separation assay. The technology in DPC's IMMULITE BR-MA and IMMULITE 2000 BR-MA is identical to technology used in previously cleared and commercially marketed IMMULITE and IMMULITE 2000 products.

IMMULITE BR-MA is a two-step sequential chemiluminescent enzyme-labeled immunometric assay, based on ligand-labeled monoclonal antibody and separation by anti-ligand-coated solid phase. The patient sample and a ligand-labeled anti-CA15-3 monoclonal antibody are simultaneously introduced into the Test Unit, containing immobilized anti-ligand, and incubated for approximately 30 minutes at 37°C with intermittent agitation. During this time, CA 15-3 antigen in the sample binds to the ligand-labeled monoclonal antibody, which, in turn, binds to the anti-ligand on the solid phase. Unbound serum is then removed by centrifugal wash. An alkaline phosphatase-labeled anti-CA 15-3 monoclonal antibody is introduced, and the Test Unit is incubated for another 30-minute cycle. The unbound enzyme conjugate is removed by a centrifugal wash. Substrate is then added, and the Test Unit is incubated for a further 10 minutes.

The chemiluminescent substrate, a phosphate ester of adamantyl dioxetane, undergoes hydrolysis in the presence of alkaline phosphatase to yield an unstable intermediate. The continuous production of this intermediate results in the sustained emission of light, thus improving precision by providing a window for multiple readings. The bound complex - and thus also the photon output, as measured by the luminometer - is proportional to the concentration of CA 15-3 in the sample.

IMMULITE 2000 BR-MA is a two-step sequential chemiluminescent enzyme-labeled immunometric assay, based on ligand-labeled monoclonal antibody and separation by anti-ligand-coated solid phase. The patient sample and a ligand-labeled anti-CA15-3 monoclonal antibody are simultaneously introduced into the Reaction Tube, containing immobilized anti-ligand, and incubated for approximately 30 minutes at 37°C with intermittent agitation. During this time, CA 15-3 antigen in the sample binds to the ligand-labeled monoclonal antibody, which, in turn, binds to the anti-ligand on the solid phase. Unbound serum is then removed by centrifugal wash. An alkaline phosphatase-labeled anti-CA 15-3 monoclonal antibody is introduced, and the Reaction Tube is incubated for another 30-minute cycle. The unbound enzyme conjugate is removed by a centrifugal wash. Substrate is then added, and the Test Unit is incubated for a further 5 minutes.

The chemiluminescent substrate, a phosphate ester of adamantyl dioxetane, undergoes hydrolysis in the presence of alkaline phosphatase to yield an unstable intermediate. The continuous production of this intermediate results in the sustained emission of light, thus improving precision by providing a window for multiple readings. The bound complex - and thus also the photon output, as measured by the luminometer - is proportional to the concentration of CA 15-3 in the sample.

The Bayer Immuno 1 CA 15-3 Assay uses a sandwich immunoassay format. 115D8 Antibody Conjugate (R1) and *mIMP*® (monoclonal ImmunoMagnetic Particle) Reagent are reacted with patient sample (or calibrator containing CA 15-3 reactive determinants) and incubated on the system at 37°C. The DF3 Enzyme Conjugate (R2) is then added. A second incubation occurs during which the antibody complex is bound. After incubation, the complex is washed and the *p*NPP (para-nitrophenyl phosphate) substrate is added. The alkaline phosphatase (ALP) in the antibody conjugate reacts with the *p*NPP to form para-nitrophenoxide and phosphate. Increasing absorbance, due to the formation of para-nitrophenoxide, is monitored at 405 nm and 450 nm.

A sample have no CA 15-3 Assay value will have the minimum label bound, while a sample having a high CA 15-3 Assay value will have maximum label bound. Thus, the dose response curve is proportional to the DF3 reactive determinants in the sample.

Performance Equivalence – Performance Characteristics:

The information in the table below provides the performance characteristics of IMMULITE and IMMULITE 2000 BR-MA and Immuno 1 CA 15-3.

Characteristics	**IMMULITE BR-MA**	**IMMULITE 2000 BR-MA**	**Immuno 1 CA 15-3**
Calibration upper limit	300 U/mL	300 U/mL	200 U/mL
Analytical Sensitivity	0.2 U/mL	0.2 U/mL	0.2 U/mL
Precision (within-run)	CV range: 5.5-8.1%	CV range: 3.7-4.9%	CV range: 1.3-3.4%
Precision (total)	CV range: 7.4-8.8%	CV range: 4.5-6.5%	CV range: 3.0-4.0%
Specificity	No significant cross-reactivity with the following compounds 5-Fluorouracil, AFP, CA 125, CA 19-9, CEA, Cisplatin, Cyclophosphamide, Doxorubicin, hydrochloride, Mitomycin C, Vincristine	No significant cross-reactivity with the following compounds 5-Fluorouracil, AFP, CA 125, CA 19-9, CEA, Cisplatin, Cyclophosphamide, Doxorubicin, hydrochloride, Mitomycin C, Vincristine	Data not available
Linearity	%Observed/Expected range: 95-105%	%Observed/Expected range: 93-104%	Data not available
Spiking Recovery	%Observed/Expected range: 89-114%	%Observed/Expected range: 92-108%	Data not available
Effect of Bilirubin (unconjugated)	No significant effect	No significant effect	No clinically significant effect
Effect of Lipemia	No significant effect	No significant effect	No clinically significant effect
Effect of Hemolysis	No significant effect	No significant effect	No clinically significant effect
High Dose Hook Effect	No effect up to 80,000 U/mL	No effect up to 80,000 U/mL	Data not available
Stability	Unopened kits kept at specified conditions are stable for 2 months. Kits are stable for one year when kept in long-term storage conditions.	Unopened kits kept at specified conditions are stable for 2 months. Kits are stable for one year when kept in long-term storage conditions.	Unopened kits kept at specified conditions are stable through the last day of the month on the product label. Long-term stability data not available.

Performance Equivalence - Method Comparison (Breast Cancer Patients and Healthy Subjects):

IMMULITE BR-MA

The IMMULITE BR-MA assay was compared to Kit A, a commercially available immunoassay that also measured CA 15-3, at two clinical sites in the northeastern and southern United States. A total of 1400 specimens from apparently healthy female subjects and pregnant women, and female patients with breast cancer, malignant and nonmalignant diseases, were evaluated at the two clinical sites. Using the 95th percentile of the normal reference ranges of the two assays (38 U/mL for IMMULITE BR-MA and 34.8 U/mL for Kit A), a qualitative comparison of the IMMULITE BR-MA and Kit A yielded the following results.

	IMMULITE BR-MA		Positive	Negative
Kit A	> 38 U/mL	≤ 38 U/mL	Agreement	Agreement
> 34.8 U/mL	334	18	94.9%	85.2%
≤ 34.8 U/mL	153	895		

Agreement: 87.8%

95% Confidence Limits for positive agreement and negative agreement, respectively: 92.0% - 96.9% and 83.3% - 87.5%.

The CA 15-3 measurements of 1307 specimens that fell within the working range of both assays (300 U/mL for IMMULITE BR-MA and 200 U/mL for Kit A) were compared in a linear regression:

IMMULITE BR-MA = 1.08 (Kit A) + 8.34 r = 0.79

95% Confidence Intervals:
Slope: 1.04, 1.13
Intercept: 6.53, 10.2

Means:
39.4 U/mL (IMMULITE BR-MA)
28.7 U/mL (Kit A)

In the clinical study conducted in the southern United States, measurements of CA 15-3 by IMMULITE BR-MA were compared to measurements by Kit B, a commercially available chemiluminescence assay for CA 27-29 on 181 specimens using the respective normal range upper limits of the two assays as the cutoff (38 U/mL for IMMULITE BR-MA and 38.6 U/mL for Kit B).

	IMMULITE BR-MA		Positive	Negative
Kit B	> 38 U/mL	≤ 38 U/mL	Agreement	Agreement
> 38.6 U/mL	63	4	94.0%	87.7%
≤ 38.6 U/mL	14	100		

Agreement: 90.1%

95% Confidence Limit for positive agreement: 85.4% - 98.4%

95% Confidence Limit for negative agreement: 80.3% - 93.1%

A subset of the specimens (n=157) within the working ranges of both assays were compared in a linear regression:

IMMULITE BR-MA = 0.86 (Kit B) + 10.4 U/mL
r = 0.95

95% Confidence Intervals:
Slope: 0.82, 0.91
Intercept: 7.61, 13.2

Means:
49.1 U/mL (IMMULITE BR-MA)
44.8 U/mL (Kit B)

IMMULITE 2000 BR-MA

The IMMULITE 2000 BR-MA assay was compared to Kit A, a commercially available immunoassay that also measured CA 15-3, at one clinical site in the northeastern United States. A total of 500 specimens from apparently healthy female subjects and pregnant women, and female patients with breast cancer, malignant and nonmalignant dieseases, were evaluated at this clinical site. Using the 95th percentile of the normal reference ranges of the two assays (38 U/mL for IMMULITE 2000 BR-MA and 34.8 U/mL for Kit A), a qualitative comparison of the IMMULITE BR-MA and Kit A yielded the following results.

	IMMULITE 2000 BR-MA		Positive	Negative
Kit A	> 38 U/mL	≤ 38 U/mL	Agreement	Agreement
> 34.8 U/mL	128	8	94.1%	84.1%
≤ 34.8 U/mL	58	306		

Agreement: 86.8%
95% Confidence Limits for positive agreement and negative agreement, respectively: 88.7% - 97.4% and 80.3% - 87.8%.

The CA 15-3 measurements of 447 specimens that fell within the working range of both assays (300 U/mL for IMMULITE 2000 BR-MA and 200 U/mL for Kit A) were compared in a linear regression:

IMMULITE 2000 BR-MA = 1.04 (Kit A) + 7.66 r = 0.85

95% Confidence Intervals:
Slope: 0.98, 1.10
Intercept: 5.37, 9.95

Means:
37.2 U/mL (IMMULITE 2000 BR-MA)
28.4 U/mL (Kit A)

In the same study, IMMULITE 2000 BR-MA was compared to IMMULITE BR-MA in a linear regression for 466 specimens that fell within the working range of both assays:

IMMULITE 2000 BR-MA = 1.02 (IMMULITE BR-MA) + 0.90 r = 0.99

95% Confidence Intervals:
Slope: 1.01, 1.04
Intercept: 0.04, 1.76

Means:
42.8 U/mL (IMMULITE BR-MA)
44.7 U/mL (IMMULITE 2000 BR-MA)

Clinical Performance:
In two clinical studies conducted in the northeastern and southern United States, serial samples from 99 breast cancer patients followed for recurrence and 80 patients followed for response to treatment were tested by IMMULITE BR-MA and compared with the clinical history of these patients.

An analysis of these cases considered IMMULITE /IMMULITE 2000 BR-MA as consistent, inconsistent, or equivocal with clinical status if over half, less than half, or exactly half of the specimens tested for a case agreed with the clinical status.

IMMULITE BR-MA measurements accurately reflected the changes in the clinical status in 80 of the 99 (81%) patients followed for recurrence. Of the remainder, 13 (13%) did not parallel the clinical status, and 6 of the 99 (6%) were equivocal as to whether CA 15-3 reflected the clinical status.

For all 294 specimens from patients followed for recurrence, the IMMULITE BR-MA measurements were compared with the clinical status of the breast cancer patients:

Clinical Status	IMMULITE >38 U/mL	IMMULITE <=38 U/mL
Active	41	16
NED*	39	198

Agreement: 81%
Sensitivity (95% CI): 72% (59-83%)
Specificity (95% CI): 84% (79-88%)
PPV* (95% CI): 51% (40-63%)
NPV* (95% CI): 93% (88-96%)

For patients followed for response to treatment, IMMULITE BR-MA measurements accurately reflected the changes in the clinical status in 53 of the 80 (66%) patients. Of

the remainder, 19 (24%) did not parallel the clinical status, and 8 (10%) were equivocal as to whether CA 15-3 reflected the clinical status.

For all 282 specimens from patients followed for response to treatment, the IMMULITE BR-MA measurements were compared with the clinical status of the breast cancer patients:

Clinical Status	IMMULITE >38 U/mL	IMMULITE <=38 U/mL
Active	191	68
NED*	10	13

Agreement: 72%
Sensitivity (95% CI): 74% (68-79%)
Specificity (95% CI): 57% (35-77%)
PPV* (95% CI): 95% (91-98%)
NPV* (95% CI): 16% (9-26%)

IMMULITE 2000 BR-MA achieved similar results in one clinical study conducted in the northeastern United States. Serial samples from 35 breast cancer patients followed for recurrence and 15 patients followed for response to treatment were tested by IMMULITE 2000 BR-MA and compared with the clinical history of these patients.

IMMULITE 2000 BR-MA measurements accurately reflected the changes in the clinical status in 28 of the 35 (80%) patients followed for recurrence. Of the remainder, 3 (9%) did not parallel the clinical status, and 4 (11%) were equivocal as to whether CA 15-3 reflected the clinical status.

For all 121 specimens from patients followed for recurrence, the IMMULITE 2000 BR-MA measurements were compared with the clinical status of the breast cancer patients:

Clinical Status	IMMULITE 2000 >38 U/mL	IMMULITE 2000 <=38 U/mL
Active	27	9
NED*	20	65

Agreement: 76%
Sensitivity (95% CI): 75% (58-88%)
Specificity (95% CI): 76% (66-85%)
PPV* (95% CI): 57% (42-72%)
NPV* (95% CI): 88% (78-94%)

For patients followed for response to treatment, IMMULITE 2000 BR-MA measurements accurately reflected the changes in the clinical status in 12 of the 15 (80%)

patients. Of the remainder, 1 (7%) did not parallel the clinical status, and 2 (13%) were equivocal as to whether CA 15-3 reflected the clinical status.

For all 67 specimens from patients followed for response to treatment, the IMMULITE 2000 BR-MA measurements were compared with the clinical status of the breast cancer patients:

Clinical Status	IMMULITE 2000 >38 U/mL	<=38 U/mL
Active	55	10
NED*	1	1

Agreement: 84%

Sensitivity (95% CI): 85% (74-92%)

Specificity (95% CI): 50% (1-99%)

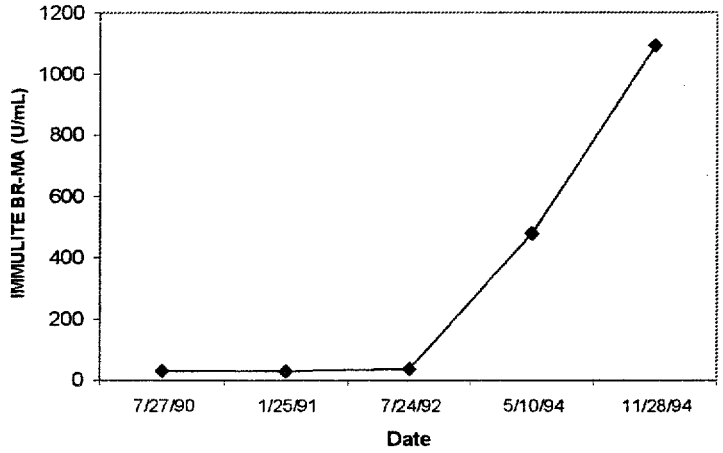
PPV* (95% CI): 98% (91-100%)

NPV* (95% CI): 9% (0-41%)

* NED – No Evidence of Disease
PPV – Positive Predictive Value
NPV – Negative Predictive Value

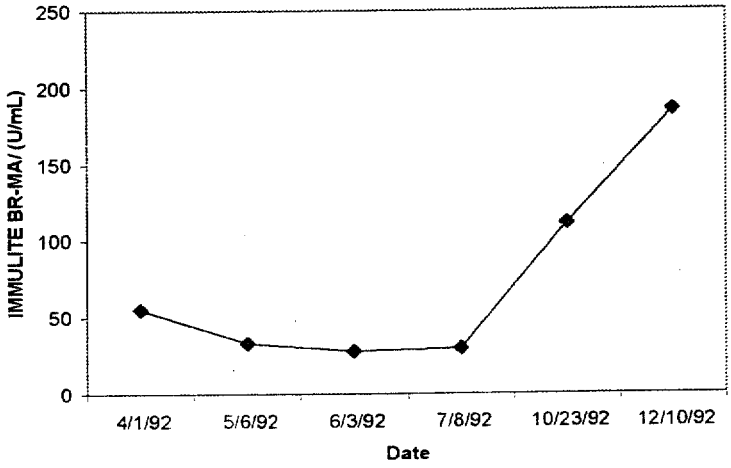
Representative profiles of patients followed for recurrent breast cancer and for response to treatment are shown in the following figures.

Monitoring of a stage II (in May 1988) breast cancer patient with IMMULITE BR-MA (CA 15-3). Longitudinal changes in IMMULITE BR-MA values correlate with changes in disease status.



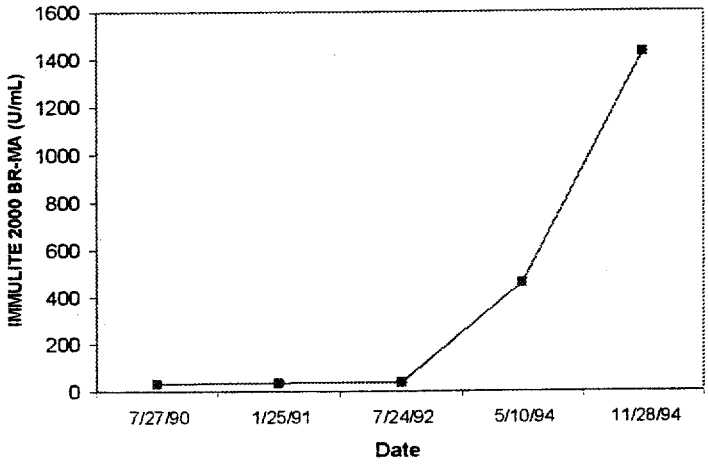
Date	U/mL	Disease Status
7/27/90	31.8	CT scan chest - negative, uncharged since 1988.
1/25/91	30.2	Ct scan chest - no evidence of metastasis.
7/24/92	37.7	Total body scan-increased tracer activity, highly suspicious for metastasis.
5/10/94	478	CT abd, pelvis - Multiple fine nodular radiodensities in lungs.
11/28/94	1092	CT chest-small bilateral pleural effusions.

Monitoring of a stage IV (in December 1989) breast cancer patient with IMMULITE BR-MA (CA 15-3). Longitudinal changes in IMMULITE BR-MA values correlate with changes in disease status and treatment.



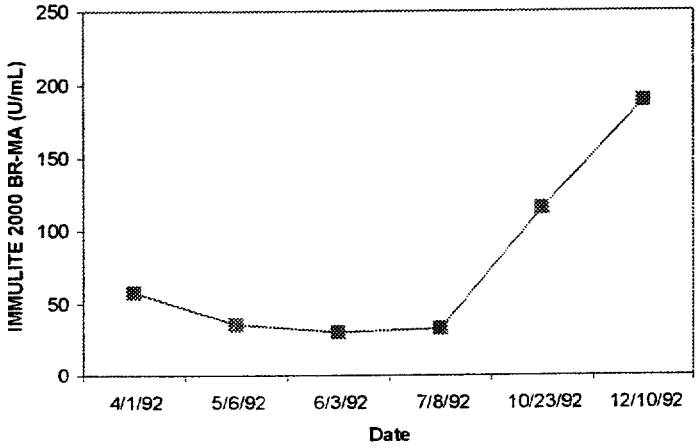
Date	U/mL	Disease Status
4/1/92	55.2	Radiation therapy 4/91 to 10/91.
5/6/92	33.1	CT showed multiple metastasis, decreasing in number and size.
6/3/92	28.0	Chemo-VAT (Virablastin, Adriamycin, Thiotepa).
7/8/92	29.6	Chest X-Ray pos; Abdominal, pelvis areas no change, stable.
10/23/92	111	Bone scan showed bone metastasis. CT scan showed marked increase in liver metastasis.
12/10/92	185	Terminal breast cancer.

Monitoring of a stage II (in May 1988) breast cancer patient with IMMULITE 2000 BR-MA (CA 15-3). Longitudinal changes in IMMULITE 2000 BR-MA values correlate with changes in disease status.



Date	U/mL	Disease Status
7/27/90	33.1	CT scan chest - negative, unchanged since 1988.
1/25/91	36.5	Ct scan chest - no evidence of metastasis.
7/24/92	38.9	Total body scan-increased tracer activity, highly suspicious for metastasis.
5/10/94	457	CT abd, pelvis - Multiple fine nodular radiodensities in lungs.
11/28/94	1426	CT chest-small bilateral pleural effusions.

Monitoring of a stage IV (in December 1989) breast cancer patient with IMMULITE 2000 BR-MA (CA 15-3). Longitudinal changes in IMMULITE 2000 BR-MA values correlate with changes in disease status and treatment.



Date	U/mL	Disease Status
4/1/92	58.1	Radiation therapy 4/91 to 10/91.
5/6/92	35.8	CT showed multiple metastasis, decreasing in number and size.
6/3/92	30.3	Chemo-VAT (Virablastin, Adriamycin, Thiotepa).
7/8/92	32.7	Chest X-Ray pos; Abdominal, pelvis areas no change, stable.
10/23/92	115	Bone scan showed bone metastasis. CT scan showed marked increase in liver metastasis.
12/10/92	189	Terminal breast cancer.

Conclusion:

The conclusions drawn from the clinical and nonclinical studies demonstrate that the device is safe, effective, and is substantially equivalent to the current legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 8 2002

Edward M. Levine, Ph.D.
Director of Clinical Affairs
Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, California 90045-5597

Re: k013984
Trade/Device Name: IMMULITE® BR-MA and IMMULITE® 2000 BR-MA
Regulation Number: 21 CFR § 866.6010
Regulation Name: Tumor Associated Antigen Immunological Test System
Regulatory Class: II
Product Code: MOI
Dated: March 4, 2002
Received: March 5, 2002

Dear Dr. Levine:

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 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" (21CFR 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,

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

510(k) Number (if known): K013984
Device Name: IMMULITE® BR-MA
IMMULITE® 2000 BR-MA

Indications For Use:

IMMULITE BR-MA
For in vitro diagnostic use with IMMULITE analyzer – for the quantitative measurement of CA 15-3 antigen in human serum, as an aid in the detection of recurrence in previously treated stage II and stage III breast cancer patients, and in the management of metastatic breast cancer patients by monitoring disease progression or response to treatment. Serial testing for patient CA 15-3 values should be used in conjunction with other clinical methods used for detecting early recurrence in Stage II and Stage III disease and for monitoring response to treatment in patients with metastatic breast cancer.

IMMULITE 2000 BR-MA
For in vitro diagnostic use with IMMULITE 2000 analyzer – for the quantitative measurement of CA 15-3 antigen in human serum, as an aid in the detection of recurrence in previously treated stage II and stage III breast cancer patients, and in the management of metastatic breast cancer patients by monitoring disease progression or response to treatment. Serial testing for patient CA 15-3 values should be used in conjunction with other clinical methods used for detecting early recurrence in Stage II and Stage III disease and for monitoring response to treatment in patients with metastatic breast cancer.

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K013984

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)