



BIOMIRA Diagnostics Inc.  
30 Meridian Road  
Rexdale, Ontario M9W 4Z7  
Canada

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**Date Submitted:**

December 20, 1996

**Device Name:**

**Trade Name:**  
TRUQUANT® BR™ RIA

**Generic Name:**  
This device does not have an official generic name.

**Classification:**  
Class II 

**Predicate Device:**  
TRUQUANT® BR™ RIA

**Device Description:**

TRUQUANT® BR™ RIA quantitates CA 27.29 by competitive inhibition RIA. <sup>125</sup>Iodine-labelled monoclonal antibody, specific for CA 27.29, is added to antigen-coated polystyrene tubes with the specimen in the form of plasma or serum. Antigen (CA 27.29) in the specimen inhibits the antibody from binding to the CA 27.29 antigen on the tube and after a subsequent wash step, bound radioactivity is determined. A calibration curve, generated from standards containing known quantities of CA 27.29, is used to determine the amount of antigen in the specimen.

**Intended Use:**

TRUQUANT® BR™ RIA is an *in vitro* diagnostic device indicated for the quantitative determination of CA 27.29 antigen in serum or EDTA plasma of patients previously treated for stage II or stage III breast cancer. Serial testing for CA 27.29 antigen with TRUQUANT® BR™ RIA in patients who are clinically free of disease should be used in conjunction with other clinical methods used for the early detection of recurrence. In addition, quantitation of CA 27.29 antigen in conjunction with other clinical methods can be used as an aid in monitoring response to therapy in patients with stage IV breast cancer.

**TRUQUANT® BR™ RIA: Monitoring of Stage IV Breast Cancer*****Summary and Conclusion***

The clinical studies support the safety and effectiveness of TRUQUANT® BR™ RIA for monitoring remission and progression in breast cancer patients with stage IV disease. Cox regression analysis of the prospective study data indicates that a 50% or greater increase or decrease in CA27.29 values from baseline, detected at least one examination prior to clinical assessment of status change, is a statistically significant predictor of disease progression or remission, respectively. The operating characteristics of the assay in the mucin-producing subset of patients (baseline marker levels above the upper limit of normal, 37.7 U/mL) provide evidence for the utility of TRUQUANT® BR™ RIA in determining response to therapy in patients with metastatic breast cancer. TRUQUANT® BR™ RIA exhibited a sensitivity of 25% (5/20) and specificity of 87% (54/62), for an accuracy of 72% (59/82), in predicting disease remission in patients with progressive or stable disease. In patients with complete or partial remission or with stable disease, TRUQUANT® BR™ RIA demonstrated a sensitivity of 52% (17/33), a specificity of 59% (10/17) and accuracy of 54% (27/50) in detecting disease progression. Furthermore, the positive and negative predictive values of 71% (17/24) and 78% (54/69) for disease progression and remission, respectively, provide clinically useful information in the management of late stage breast cancer. A marker increase of 50% or more suggests a high probability of treatment failure and likelihood of disease progression; a marker decrease of less than 50% is also associated with ineffective therapy and failure to induce remission.

In medical practice, the premature withdrawal of effective therapy or prolonged maintenance of ineffective treatment are critical consequences predicated on accurate assessment of patient status. TRUQUANT® BR™ RIA can facilitate important clinical decisions through surveillance of soluble marker levels in metastatic breast cancer patients whose tumors produce and secrete mucin (CA27.29).

***Conclusion:*** TRUQUANT® BR™ RIA, when used in conjunction with other clinical criteria, can assist the clinician in determining response to therapy and in management of breast cancer patients with stage IV disease.



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Bo Hollas  
Manager QA/Regulatory  
Biomira Diagnostics, Inc.  
30 Meridian Road  
Rexdale, Ontario, CANADA

OCT 31 1997

Re: K965141  
Trade Name: TRUQUANT® BR™ RIA  
Regulatory Class: II  
Product Code: MOI  
Dated: October 16, 1997  
Received: October 17, 1997

Dear Ms. Hollas:

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.

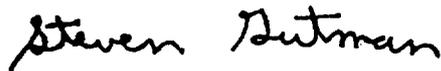
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 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): K965141

Device Name: \_\_\_\_\_  
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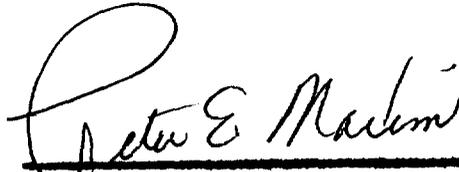
**Indications For Use:**

**2.3 Intended Use**

TRUQUANT® BR™ RIA is an *in vitro* diagnostic device indicated for the quantitative determination of CA 27.29 antigen in serum or EDTA plasma of patients previously treated for stage II or stage III breast cancer. Serial testing for CA 27.29 antigen with TRUQUANT® BR™ RIA in patients who are clinically free of disease should be used in conjunction with other clinical methods used for the early detection of recurrence. In addition, quantitation of CA 27.29 antigen in conjunction with other clinical methods can be used as an aid in monitoring response to therapy in patients with stage IV breast cancer.

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K965141

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)