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**dbc - DIAGNOSTICS BIOCHEM CANADA INC.**
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DATE: November 29, 2001

Contact Person: Dr. G. R. Dumont
Tel (519) 681-8731

## 18. 510 K Summary

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

1. The assigned 510K number is K014120

2. The classification name of the device: enzyme immunoassay for testosterone

3. Classification number 862.1680

4. Proprietary name: Testosterone By Enzymeimmunoassay (EiA)
Class I

5. Use of the device
Direct determination of Testosterone (total) by enzymeimmunoassay (Elisa) in human serum

6. The predicate device's name and address of which we claim equivalence:
Diagnostics System Laboratories,(DSL) 445 Medical Center Blvd. Webster, Texas, 77598
DSL 10-4000 Active™
Testosterone Enzymeimmunoassay (EiA) kit
510(K) #971823

7. The Testosterone (total) Elisa kit consists of one polyclonal antibody which is coated on microtiter plate (96 wells per kit). The antigen Testosterone 3 carboxymethyl oxime is conjugated to an enzyme namely horse radish peroxidase. The standards are prepared from protein base matrix and all other reagents within a kit namely assay buffer, wash buffer concentrate, substrate tetramethytbenzidine (TMB) and stopping solution. The incubation time is 60 minutes at room temperature. 25 ul of patient serum , control serum and each standard are added for each assay. After incubation the plates are washed 3 times, each time with 300 ul of diluted wash buffer. The plates are dried. 150 ul of TMB is added to each well and allowed to incubate for 10 - 15 minutes. 50 ul of stopping solution is added into each well and the colour becomes yellow. The plate is read within 20 minutes in a microtiter plate reader at 450 nm.

9. Substantial equivalence:

1. The dbc In-vitro diagnostic device namely Testosterone (total) by enzymeimmunoassay (EiA) has the same intended use as current device on the market referred to "predicate device".

2. The dbc In-vitro diagnostic device namely Testosterone (total) by enzymeimmunoassay (EiA) has the same technological characteristics as predicate device namely Enzymeimmunoassay (EiA) antigen/antibody.

3. The dbc enzymeimmunoassay for total testosterone has no new technological feature which will raise questions of safety and effectiveness.

4. The data obtained help to indicate substantial equivalency and the results of a number of human serum samples. The results need not be exactly the same but a collaboration of equivalence is necessary in this case r=0.958.

5. The dbc total testosterone safety and effectiveness compared to the predicate devices can be found in our results of performance characteristics namely; sensitivity, specificity, Intra and Inter assay precision, Recovery and Linearity.

6. dbc total testosterone intended use, methodology, reagents and materials including equipments and control necessary to perform the test are similar to the predicate device. From our assay data and protocol the safety and effectiveness of dbc total testosterone is similar to the predicate device.

7. Our 510K presentation demonstrates substantial equivalence to predicate device in regards:

- intended use
- design
- performance
- material and equipments
- safety
- effectiveness
- standards
- control

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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G.R. Dumont, M.D., M.SC.
Director of Laboratories
Diagnostics Biochem Canada, Inc.
1020 Hargrieve Road
London, Ontario, N6E 1P5
Canada

Re: k014120
Trade/Device Name: EiAsy™ Testosterone EiA
Regulation Number: 21 CFR 862.1680
Regulation Name: Testosterone test system
Regulatory Class: Class I
Product Code: CDZ
Dated: November 16, 2001
Received: December 17, 2001

Dear Dr. Dumont:

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

## Statements of Indication for Use

**510K number** K014120

**Device Name: EiAsy™ Testosterone EiA**

**Indication for Use:**

The dbc CAN-TE-250 EiAsy™ Testosterone enzymeimmunoassay (EiA) kit **provides the reagents necessary for the direct determination of Testosterone in human serum The use of this assay is intended for in vitro diagnostic use only. Measurement of Testosterone are used in the diagnosis and treatment of disorders involving the male sex hormone (androgens), including primary and secondary hypogonadism, delayed or precocious puberty impotence in male and in females hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries and adrenogenital syndromes.**

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K014120

**Prescription USE.....X.....** **Or** **Over-The-Counter Use.....**
**(Per 21 CFR 801.109**

Susan S. Alpaine

**(Division Sign-Off)**
**Division of Clinical Laboratory Devices**
**510(k) Number** K014120