JUN 29 1998

K981243

Biostride, Inc.

510(k) Summary

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

1. Date of summary: April 2, 1998

2. Submitted by: Biostride Diagnostics Inc., 1201 Douglas Ave. Redwood City, CA 94063

TEL 650-367-4954
FAX 650-364-4985
Contact: George Nokes or Laura Colin

3. Device Name: Biostride Free T4 EIA Test, Test kit to determine the quantitative estimation of Free T4 in human serum

4. Device Classification: Class II, 75-CEC, CFR (862.1695)

5. Device description: The Biostride Free T4 EIA Test Kit is an *in vitro* enzyme immunoassay for the quantitative estimation of freeT4, thyroxine, in human serum. This Free T4 test is a colorimetric microtiter plate enzyme immunoassay (EIA).

6. Intended Use: The Biostride Free T4 EIA Test is an *in vitro* enzyme immunoassay for the quantitative estimation of free T4, thyroxine, in human serum.

7. Substantial Equivalence: The Biostride FT4 EIA was compared to the Abbott AxSYM.

The Biostride Free T4 test is a colorimetric microtiter plate enzyme immunoassay (EIA) for the estimation of Free T4 in human serum. Patient samples and rabbit Anti T4 are pipetted into a microtiter well coated with Goat-Anti-Rabbit IgG. After a 20 minute incubation T4-HRP tracer is added and incubated for 20 minutes, followed by a wash with tap water. The formation of blue color is obtained with the addition of the TMB/H_2O_2 substrate. 2N HCl is added to stop the enzyme/substrate reaction, giving a yellow color. Color intensity is measured as absorbance on a microtiter plate reader at 450 nm. The absorbance value is indirectly proportional to the concentration of Free T4 in the sample. The Abbott AxSYM is an MEIA, Microparticle Enzyme immunoassay, which combines human serum containing T4 and anti-T4 sheep microparticles. The T4 bound microparticles are transferred and irreversibly bound to a glass fiber matrix. The Abbott system uses an alkaline phosphatase conjugate tracer and a 4-Methylumbelliferyl Phosphate substrate. The Abbott method measures a fluorescent product, which is indirectly proportional to the concentration of Free T4. The Abbott system is an automated procedure including sample processing, testing and reporting.

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Both products have the same intended use, i.e., enzyme immunoassays for the quantitative estimation of Free T4 in human serum. Both test systems use several standard curve calibrators to interpret patient samples and report the result in ng/dL.

The products demonstrated similar performance characteristics and excellent correlation of results.

171 patient samples were evaluated to compare the results of the two tests. The correlation results were as follows:

Intercept	Slope	Correlation Coefficient(r)
0.13 ng/dL	0.91	0.96

Performance Characteristics were similar in the two products as follows:

- Biostride demonstrated precision CVs of 6%, 3% and 2% and reproducibility CVs of 9%, 5% and 4%. The Abbott system reported precision CVs between 2.10-9.9%
- The sensitivity defined as the concentration of 2 SD from the 0.0 g/dL calibrator was 0.08ng/dL for Biostride and 0.04ng/dL for AxSYM.
- Specificity to D-T4 was similar at approximately 100% for both products

Conclusion

The Biostride Free T4 EIA Test Kit and the Abbott AxSYM are substantially equivalent in performance characteristics, intended use, and assay principle.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 29 1998

Janis Freestone
Charlton Associates
1206 Sesame Drive
Sunnyvale, California 94087

Re: K981243
Biostride Free T4 EIA Test Kit
Regulatory Class: II
Product Code: CEC
Dated: June 9, 1998
Received: June 11, 1998

Dear Ms. Freestone:

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 requirements, 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.

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 (301) 443-6597 or at its internet address "dsmo@fdadr.cdrh.fda.gov".

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

INDICATIONS FOR USE STATEMENT

510k number (if known): K981243
Device Name: Biostride Free T4 EIA Test Kit

Indications for use:
This Enzyme immunoassay is used for the quantitative estimation of non-protein bound thyroxine(Free T4) in human serum. This is an *in vitro* diagnostic device used to assist in the assessment of thyroid function.

(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 Clinical Laboratory Devices
510(k) Number K981243

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

(Optional Format 1-2-96)