

FEB - 2 1998

10.0 510(K) SUMMARY

A 510(k) Summary follows for the AuraFlex® FT3 reagents described in this submission.

**510(k) Summary
AuraFlex® FT3**

This summary and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Submitter's Name: Alfa Biotech (UK) Ltd

Submitter's Address: Unit 4, Spring Lakes Estate, Deadbrook Lane, Aldershot,
Hants, GU12 4UH

Submitter's Telephone: (44) 1252 341477

Submitter's Contact: Mr M John Taylor

Date 510(k) Summary Prepared: September 26, 1997

Device Trade or Proprietary Name: AuraFlex® FT3

Device Common or Usual Name: Immunoassay for free triiodothyronine

Device Classification Name: Free triiodothyronine Test System

Device Description: Fluorescent immunoassay reagents.

Device Intended Use: The AuraFlex® FT3 assay is a fluorescent immunoassay for the quantitative determination of free triiodothyronine assay in human serum or plasma using the AuraFlex® System.

Data Upon Which Substantial Equivalence was Determined:

A comparison study was conducted in which 110 human serum samples were assayed using the AuraFlex® FT3 assay in singlicate. Results between the two assays showed a correlation of 0.9 (AuraFlex® FT3 = 0.93 Other FT3 assay +0.2pg/ml (0.3 pmol/l)).



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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M. John Taylor
Director of Quality and Regulatory Affairs
Alfa Biotech (UK) Ltd.
4 Spring Lakes Estate
Deadbrook Lane
Aldershot
Hants GU12 4UH

Re: K974027
AuraFlex® FT3
Regulatory Class: II
Product Code: CDP
Dated: January 21, 1998
Received: January 21, 1998

Dear Mr. Taylor:

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.

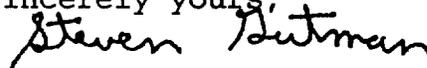
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 (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): K974027

Device Name: AURAFLEX FT3

Indications for Use:

AuraFlex FT3 employs a fluorescent enzyme immunometric assay technology for the quantitative determination of free triiodothyronine (FT₃) in human serum or plasma using the AuraFlex system.

(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)


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K974027