

NOV 29 1996 510(k) Summary



K962760

Introduction According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact Boehringer Mannheim Corporation
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2) Device name Proprietary name: Enzymun-Test® FT3
Common name: free triiodothyronine test system

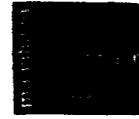
3) Predicate device We claim substantial equivalence to the Diagnostic Products Corp. FT3.

4) Device Description The Enzymun FT3 employs a competitive test principle with polyclonal antibodies directed against T3 and with streptavidin tubes .

- 1st Incubation: Sample (100 µl) and a specific anti-T3 antibody are added to the streptavidin tube and all the FT3 present in the sample binds to the anti-T3 antibody-POD conjugate.
- 2nd Incubation: Incubation buffer (biotinylated T# polyhaptens) is added and binds with excess anti-T3 antibody-POD conjugate to the wall of the streptavidin tube.

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4) Device Description, cont.

- In the separation step, serum or plasma FT3-anti-T3 antibody-POD conjugate, excess biotinylated T3 polyhapten and serum constituents are removed.
- The activity of the POD bound to the tube wall is determined photometrically after the addition of the chromogen and the substrate H₂O₂ (from sodium perborate). In the indicator reaction, the chromophore formed is a dark green cation whose concentration is indirectly proportional to the FT3 concentration in the sample. Results are determined via a calibration curve.

5) Intended use

For the *in vitro* quantitative determination of free triiodothyronine (FT3) in human serum and plasma.

6) Indications for use

T3 is biologically the most important thyroid hormone and has been shown to be four to five times more potent than T4. At least 80% of T3 is derived from the deiodination of T4 by the liver and other peripheral tissues rather than from direct secretion by the thyroid.

Since T3 and T4 are poorly soluble in plasma, 70% to 75% are transported by thyroid binding globulin (TBG), a plasma protein. A very low concentration of free T3 (FT3) and free T4 (FT4) exist in equilibrium in plasma with their protein-bound counterparts. However, it is the FT3 and FT4 that are the physiologically active thyroid hormones.. Only these free hormones can bind to receptors on cell surfaces. The cell then converts FT4 to FT3 which can deliver its hormonal message by reacting with DNA.

Circulating FT3 is found in very small quantities (the ratio of FT3 to total T3 is 1:300, or about 0.3% of total serum T3). FT3 and FT4 tend to parallel changes in total T3 and T4, and are not affected by abnormal TBG concentrations.

FT3 measurements are used in the diagnosis and treatment of thyroid diseases. It should be noted that increases and decreases of FT3 and FT4 more accurately reflect hyperthyroidism and hypothyroidism. As such, FT3 is very useful when other tests reflect borderline or conflicting results.

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6) Comparison to predicate device

The Boehringer Mannheim Elecsys FT3 is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Diagnostic Products Corporation FT3.

Similarities:

- Intended use: immunoassay for the *in vitro* quantitative determination of free triiodothyronine (FT3)
- Competitive test principle
- Sample type and volume: serum and plasma, 100µl
- Standardization: weighed in standards

Differences:

Feature	Enzymun FT3	DPC FT3
Reaction test principle	streptavidin microparticles and electrochemiluminescence technology	solid phase radioimmunoassay technology
Instrument required	ES 300	gamma counter
Measuring range	0.5 to 30 pg/mL	0.5 to 42 pg/mL