K962231

Roche Diagnostic Systems
A Member of the Roche Group

AUG 30 1996

Roche Diagnostic Systems, Inc
Branchburg Township
1080 U.S. Highway 202
Somerville, New Jersey 08876-3771

Direct Dial
Fax

510(k) Summary

Roche COBAS Core II Immunochemistry System

In accordance with the Safe Medical Devices Act of 1990, a 510(k) summary as outlined in 21 CFR 807.92 is provided herewith.

I. Identification of 510(k) Sponsor:

Roche Diagnostic Systems, Inc.
a subsidiary of Hoffmann-La Roched, Inc.
Branchburg Township
1080 US Highway 202
Somerville, NJ 08876-3771

510(k) Submission dated June 7, 1996

II. Description of the Device/Statement of Intended Use:

The COBAS Core II Immunochemistry System is an *in vitro* diagnostic analyzer intended for enzymeimmunoassay procedures. The instrument performs initial sample measurement and pipetting, timed addition of assay reagents, incubation and shaking of assay tubes, aspiration of used reagents and washing of coated polystyrene assay beads and photometric measurement of the chromogen / enzyme reaction.

III. Identification of the legally marketed device to which the 510(k) sponsor claims equivalence:

The COBAS Core II Immunochemistry System is substantially equivalent to the currently marketed Roche COBAS Core Immunochemistry System (K921180).

IV. Summary of the technological characteristics of the new device in comparison to those of the predicate.

Similarities to predicate

- Both instruments are intended for automation of the currently marketed Roche COBAS Core assays:

COBAS Core Ferritin (K920829)	COBAS Core TSH (K930776)
COBAS Core Prolatin (K930305)	COBAS Core T4 (K932605)
COBAS Core FSH (K930304	COBAS Core T3 (K932608)
COBAS Core LH (K930306)	COBAS Core Free T4 (K932607)
COBAS Core IgE (K930890)	COBAS Core Free T3 (K942676)

- Both instruments perform the same basic operations, which are, sample handling, pipetting, dilution, incubation, bead washing, measurement and data management.
- Both instruments utilize the coated bead technology and photometric measurement.

Differences to predicate device
The differences in the above mentioned devices consist hardware and software changes in the following areas:

Area of Change	COBAS Core I	COBAS Core II
Barcode Reader	Infra Red Reader	Laser Barcode Scanner
Rack Platform	6 positions for samples and reagents	14 positions for samples and reagents
Test /Sample Racks Identity	Binary Rack Coding	Barcode Label ID
Rack Locking Device	Racks could be unlocked during processing	Racks are mechanically locked when in use
Pipetting Syringes	Module on left side of instrument	Module moved to the right side of the instrument with no modification to the tube length or syringes
Operating Software	Internally developed software	Internally developed software embedded in Microsoft Windows NT
Microprocessor	CPU 186	PC- 486 DX33 Real Time CPU 186 Hard Disk - 350 MB RAM - 16 MB Diskette - 1.44 MB floppy disk drive 3.5"

V. Breif discussion of the clinical and nonclinical tests relied on for a determination of substantial equivalence:

To demonstrate equivalence in performance characteristics, three representative assays were evaluated for precision and accuracy. The three assays are:
COBAS Core LH
COBAS Core FSH
COBAS Core Ferritin

Precision Study
Four internal reference sera and the kit control were tested to evaluate the within-run and run-to-run reproducibility of the COBAS Core II analyzer. For within-run precision the samples were tested seven times in triplicate. For the run-to run precision the same samples were tested in duplicate in 10 independent runs. Except for one serum with a very low LH level, all CV's are far below 10%. The precision range found for the COBAS Core II correspond to the values determined for the COBAS Core I.

Correlation Study
The correlation of the COBAS Core I and COBAS Core II was evaluated using 137 randomly selected clinical samples run in duplicate on both analyzers. The results of Core I and Core II were compared using linear regression analysis. For all three assays, the calculated slopes were 1.000 ± 0.014 with a correlation coefficient > 0.995.