

510(k) Summary - ELECSYS® Cortisol on ELECSYS® Immunoassay Analyzers

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

Submitter name, address, contact Roche Diagnostics Corporation
9115 Hague Rd
Indianapolis IN 46250
(317) 521-3831

Contact person: Sherri L. Coenen

Date prepared: April 16, 2002

Device Name Proprietary name: ELECSYS® Cortisol Assay

Common name: Cortisol test

Classification name: Fluorometric, cortisol

Device description The ELECSYS® Cortisol Assay a two step sandwich immunoassay with streptavidin microparticles and electrochemiluminescence detection.

Results are determined using a calibration curve that is generated specifically on each instrument by a 2-point calibration and a master curve provided with the reagent bar code.

510(k) Summary - ELECSYS® Cortisol on ELECSYS® Immunoassay Analyzers, continued

Intended use	Immunological in vitro assay for the quantitative determination of cortisol in human serum, plasma and urine.
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Indication for use	The determination of cortisol is used for the recognition and treatment of functional disorders of the adrenal gland.
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Substantial equivalence	The ELECSYS Cortisol test is equivalent to other devices legally marketed in the United States. We claim equivalence to the Bayer Diagnostics ACS:180 Cortisol Assay (K962559).
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510(k) Summary - ELECSYS® Cortisol on ELECSYS® Immunoassay Analyzers, continued

Substantial equivalence - similarities

The following table compares the ELECSYS® Cortisol, with the Predicate Devices.

Feature	New Device ELECSYS Cortisol	Predicate Device Bayer ACS:180 Cortisol
Intended use	<p>Immunological in vitro assay for the quantitative determination of cortisol in human serum, plasma, and urine. The determination of cortisol is used for the recognition and treatment of functional disorders of the adrenal gland.</p> <p>The electrochemiluminescence immunoassay "ECLIA" is intended for use on Roche Elecsys 1010/2010 and Modular Analytics E170 (Elecsys module) immunoassay analyzers.</p>	<p>For the quantitative determination of cortisol in serum or urine using the Chiron Diagnostics ACS:180 Automatic Chemiluminescence Systems.</p> <p>For In Vitro Diagnostic use.</p>
Sample type	serum, plasma, urine	serum, urine
Assay Protocol	competition assay	competition assay
Detection Protocol	electrochemiluminescence	direct chemiluminescence

Substantial equivalence – differences

The following table compares the ELECSYS® Cortisol with the Predicate Device.

Feature	New Device ELECSYS Cortisol	Predicate Device Bayer ACS:180 Cortisol
Measuring range	1.0 – 1750 nmol/L	5.5 - 2069 nmol/L
Expected values	Urine 36 – 137 ug/24 hrs	Urine 12.1 – 103.8 ug/24 hrs
Instrument	Elecsys immunoassay analyzers	ACS:180 automated chemiluminescence system

510(k) Summary - ELECSYS® Cortisol on ELECSYS® Immunoassay Analyzers, continued

**Substantial
equivalence –
performance
characteristics**

The performance characteristics of the ELECSYS Cortisol and the Predicate Device are compared in the table below.

Feature	New Device ELECSYS Cortisol	Predicate Device Bayer ACS:180 Cortisol
Intra-assay precision (%CV)	Urine <ul style="list-style-type: none"> • 2.2% at 22.3 µg/dl • 2.3% at 33.2 µg/dl • 2.9% at 41.9 µg/dl • 2.3% at 61.0 µg/dl 	<ul style="list-style-type: none"> • 5.7% at 3.04 µg/dl • 5.1% at 5.43 µg/dl • 4.5% at 14.90 µg/dl • 6.4% at 18.98 µg/dl • 7.0% at 31.79 µg/dl • 7.5% at 38.67 µg/dl
Interassay precision (%CV)	Urine <ul style="list-style-type: none"> • 2.5% at 23.2 µg/dl • 3.2% at 33.4 µg/dl • 2.5% at 42.1 µg/dl • 1.8% at 58.9 µg/dl Control <ul style="list-style-type: none"> • 4.7% at 2.82 µg/dl 	N/A
Total precision (%CV)	N/A	<ul style="list-style-type: none"> • 9.1% at 3.04 µg/dl • 8.0% at 5.43 µg/dl • 6.4% at 14.90 µg/dl • 8.2% at 18.98 µg/dl • 9.2% at 31.79 µg/dl • 9.7% at 38.67 µg/dl

510(k) Summary - ELECSYS® Cortisol on ELECSYS® Immunoassay Analyzers, continued

Substantial
equivalence –
performance
characteristics,
continued

The performance characteristics of the ELECSYS Cortisol and the Predicate Device are compared in the table below.

Feature	New Device ELECSYS Cortisol	Predicate Device Bayer ACS:180 Cortisol
Functional sensitivity	< 0.29 µg/dl	0.2 µg/dl
Limitations	When performed in urine, the assay is unaffected by: <ul style="list-style-type: none"> • 60 mg/dl protein • 750 mmol/l NaCl • 350 mmol/l urea • 5 mmol/l creatinine • 2 mmol/l glucose 	When performed in urine, the assay is unaffected by: <ul style="list-style-type: none"> • 60 mg/dl protein • 750 mmol/l NaCl • 350 mmol/l urea • 5 mmol/l creatinine • 2 mmol/l glucose
On-board stability	<ul style="list-style-type: none"> • Elecsys® 2010 / E170: 6 weeks • Elecsys® 1010: 6 weeks (stored alternately in refrigerator and analyzer at ambient temperature 20-25 C) Up to 20 hr. opened in total 	until expiration date on the vial label or cumulative 32 hrs at room temperature.

510(k) Summary - ELECSYS® Cortisol on ELECSYS® Immunoassay Analyzers, continued

Substantial
equivalence –
performance
characteristics,
continued

The performance characteristics of the ELECSYS Cortisol and the Predicate Device are compared in the table below.

Feature	New Device ELECSYS Cortisol	Predicate Device Bayer ACS:180 Cortisol
Calibration frequency	<ul style="list-style-type: none"> • Elecsys® 2010 / E170: <ul style="list-style-type: none"> • Once per reagent lot • after one month (using the same reagent lot) • after 7 days (using the same reagent kit on the analyzer) • Elecsys® 1010 <ul style="list-style-type: none"> • With every reagent kit • after 7 days (using the same reagent kit, ambient temperature 20 - 25°C) • after 3 days (using the same reagent kit, ambient temperature 25 - 32°C) • Controls out of range (both systems) 	<ul style="list-style-type: none"> • every 7 days • when changing lot numbers of assay reagents • when replacing system components • when quality control results are repeatedly out of range



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Sherri L. Coenen
Regulatory Submissions, Centralized Diagnostics
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

SEP 9 2002

Re: k021218
Trade/Device Name: ELECSYS® Cortisol Test System
Regulation Number: 21 CFR 862.1205
Regulation Name: Cortisol (hydrocortisone and hydroxycorticosterone) test system
Regulatory Class: Class II
Product Code: JFT
Dated: July 19, 2002
Received: July 23, 2002

Dear Ms. Coenen:

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.

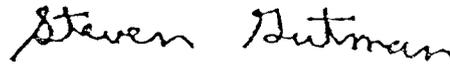
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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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 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

510(k) Number (if known): N/A

Device Name: ELECSYS® Cortisol Test System

Indications For Use:

Immunological in vitro assay for the quantitative determination of cortisol in human serum, plasma and urine. The determination of cortisol is used for the recognition and treatment of functional disorders of the adrenal gland.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Roche Elecsys® 1010 / 2010 and Modular Analytics E170 (Elecsys module) Immunoassay Analyzers.



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021218

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use OR Over-The-Counter Use
(Per 21 CFR 801.109)

2-96)

(Optional Format 1-