

K982087

AUG 18 1998



Roche
Diagnostic
Systems

510(k) Summary

Roche® CRP T Control N

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

The assigned 510(k) number is: K982087

I. Identification of 510(k) Sponsor:

Roche Diagnostic Systems, Inc.
a subsidiary of Hoffmann-La Roche, Inc.
Branchburg Township
1080 U.S. Highway 202
Somerville, New Jersey 08876-3771

510(k) Submission dated: June 12, 1998

Contact: Rita Smith
Senior Regulatory Affairs Associate
Phone: (908) 253-7545
Fax: (908) 253-7547

II. Device Name:

The device name, including both the trade/proprietary name and the classification name are provided in the table below.

Table 1

Product Name	Classification Name	Product Code	CFR Number and Regulatory Class
Roche CRP T Control N	C-reactive protein, antigen, antiserum and control	DCK	866.5270 Class II

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

The following table identifies the legally marketed devices to which Roche Diagnostic Systems, Inc. claims equivalence.

Table 2

Product Name	Predicate Product Name	Date Predicate Cleared	Predicate 510(k) Number
Roche CRP T Control N	Behring Diagnostics N/T Rheumatology Control SL 1 / 2	7/11/96	K962373

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

Roche CRP T Control N is an assayed control intended for use to monitor the accuracy and precision at normal concentration levels in quantitative C-reactive protein (CRP) assays. It is recommended for use with Roche reagents on COBAS® chemistry systems.

Roche CRP T Control N is part of a C-reactive protein immunological test system, which is used to measure, by immunochemical techniques, the C-reactive protein in serum and other body fluids. Measurement of C-reactive protein aids in evaluation of the amount of injury to body tissues.

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

The Roche CRP T Control N and the Behring N CRP Control are both human serum based controls with assayed values for C-reactive protein and intended for use in monitoring accuracy and precision in quantitative C-reactive protein (CRP) assays.

	Roche CRP T Control N	Behring Diagnostics N/T Rheumatology Control SL 1/ 2	
Matrix/Biological Sources	Liquid human serum	Liquid human serum	
Concentration Range (mg/L)	3.44 - 4.66	Level 1	Level 2
		9.0 - 12.2	40.3 - 54.5

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

No clinical or nonclinical tests were performed for this product.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 18 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Rita Smith
Senior Regulatory Affairs Associate
Roche Diagnostic Systems, Inc.
Hoffmann-La Roche, Inc.
1080 U.S. Highway 202
Somerville, New Jersey 08876-3771

Re: K982087
Trade Name: Roche® CRP T Control N
Regulatory Class: II
Product Code: DCK
Dated: June 12, 1998
Received: June 15, 1998

Dear Ms. Smith:

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 requirement, 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.

Page 2

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 at (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) K 982087

Device Name: Roche CRP T Control N, Art. No. 07 6632 1

Indications for Use:

Roche CRP T Control N is an assayed control intended for use to monitor the accuracy and precision at normal concentraion levels in quantitative C-reactive protein (CRP) assays. It is recommended for use with Roche reagents on COBAS® chemistry systems.

Roche CRP T Control N is part of a C-reactive protein immunological test system, which is used to measure, by immunochemical techniques, the C-reactive protein in serum and other body fluids. Measurement of C-reactive protein aids in evaluation of the amount of injury to body tissues.

(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)

Peter E. Masperi

(Division) _____
Date _____
510(k) Number _____

510(k) Checklist
Premarket Notification