JUN 1 0 2002

K021381

510(k) Summary
N/T Rheumatology Controls SL

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:

Manufacturer:	Dade Behring Marburg GmbH Emil-von-Behring Str. 76 Marburg/Germany
Contact Information:	Dade Behring Inc. Glasgow Site P.O. Box 6101 Newark, Delaware 19714 Attn: Donna Wolf Tel: 302-631-0384
Preparation date:	May 30, 2002

2. Device Name/ Classification:

N/T Rheumatology Controls SL 1 & 2:	Quality Control Material (assayed)
Classification Number:	Class I (862.1660)

3. Identification of the Legally Marketed Device:

N/T Rheumatology Controls SL 1 & 2 (K962373)

4. Device Description:

N/T Rheumatology Controls SL (bi-level control; N/T Rheumatology Control SL/1 and N/T Rheumatology Control SL/2) is a multi-constituent control intended for use as a quality control material to monitor the accuracy and precision of selected rheumatic and inflammatory disease with the BN and Behring TurbiTime Systems.

5. Device Intended Use:

N/T Rheumatology Controls are assayed controls for accuracy and precision in the quantitative determination of rheumatoid factors (RF), anti-streptolysin O (ASL) and C-reactive protein (CRP) in human serum using BN* Systems and the TurbiTimeSystem.

6. Medical device to which equivalence is claimed and comparison information:

The N/T Rheumatology Controls SL (modified) is substantially equivalent to its predicate version (K962373). Modification of the intended use statement to include the use of Rheumatoid Factor determination with the TurbiTime System is the subject of this submission. Additionally, N/T Rheumatology Controls SL/2 will no longer be used for ADNase B determinations.

7. Device Performance Characteristics:

Stability:
Stability was evaluated according to Dade Behring protocols and the control was found to be stable for at least 18 months at +2° to +8° C, as originally packaged and for at least 21 days at +2° to +8° C, once opened.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 1 0 2002

Ms. Donna Wolf
Senior Regulatory Affairs Specialist
Dade Behring, Inc.
Glasgow Site
P.O. Box 6101
Newark, Delaware 19714

Re: k021381
Trade/Device Name: N/T Rheumatology Controls SL
Regulation Number: 21 CFR § 862.1660
Regulation Name: Quality Control Material (assayed)
Regulatory Class: I
Product Code: JJY
Dated: April 30, 2002
Received: May 1, 2002

Dear Ms. Wolf:

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.

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 Gutman

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

Device Name: N/T Rheumatology Controls SL

Indications for Use:

N/T Rheumatology Controls are assayed controls for accuracy and precision in the quantitative determination of rheumatoid factors (RF), anti-streptolysin O (ASL) and C-reactive protein (CRP) in human serum using BN* Systems and the TurbiTimeSystem.

Susan S Alfaro

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K021381

(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)

Over-The-Counter-Use _____

(Optional Format 1-2-96)