

APR 10 2000

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
 D. Bilirubin method for ADVIA® 400

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K993867

1. Intended Use

This *in vitro* diagnostic method is intended to measure D. Bilirubin (a product formed during the normal and abnormal destruction of red blood cells) in human serum or plasma on the Bayer ADVIA 400 system

2. Predicate Device

| Product Name | Reagent Part # | Calibrator Part # |
|--------------------------------|----------------|-------------------|
| Technicon CHEM 1® D. Bilirubin | T01-1522-53 | T03-1291-62 |

3. Device / Method

| Product Name | Reagent Part # | Calibrator Part # |
|------------------------|----------------|-------------------|
| ADVIA 400 D. Bilirubin | B41-3723-46 | T03-1291-62 |

A. Imprecision(SERUM)

| ADVIA 400 | | CHEM 1 | |
|---------------|-------------|---------------|-------------|
| Level (mg/dL) | Total CV(%) | Level (mg/dL) | Total CV(%) |
| 0.7 | 9.0 | 0.2 | n/a |
| 5.5 | 3.4 | 5.0 | 3.9 |
| 11.8 | 3.3 | 8.3 | 3.2 |

Correlation (Y=ADVIA 400, X=comparison system)

| Specimen type | Comparison System (X) | N | Regression Equation | Syx (mg/dL) | r | Sample Range (mg/dL) |
|---------------------|-----------------------|----|---------------------|-------------|-------|----------------------|
| Serum | CHEM 1 | 59 | Y=0.98X-0.10 | 0.19 | 0.994 | 0.0 – 10.6 |
| Plasma(y), Serum(x) | ADVIA 400 | 59 | Y=0.89X+0.06 | 0.03 | 0.852 | 0.09 – 0.42 |

Interfering Substances

| Interfering Substance | Interfering Sub. Conc. (mg/dL) | D. Bilirubin Conc. (mg/dL) | Effect (% change) |
|------------------------|--------------------------------|----------------------------|-------------------|
| Hemoglobin | 500 | 0.9 | -17 |
| Lipids (Triglycerides) | 500 | 1.8 | -69 |

Analytical Range

Serum/Plasma: 0 to 14 mg/dL

Gabriel J. Murray Jr.
 11/4/99

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
HbA1c Method for ADVIA IMS**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____ (leave blank)

1. Intended Use

This in vitro method is intended to quantitatively measure %HbA1c in human blood on the Bayer ADVIA IMS systems. Measurements of %HbA1c are used to aid in the diagnosis and for monitoring the long term care of persons with diabetes.

2. Predicate Device

| Product Name | Reagent Part # | Calibrator Part # |
|---------------------|----------------|-------------------|
| Bayer RA-1000 HbA1c | T01-3639-01 | T03-3644-01 |

3. Device / Method

| Product Name | Reagent BAN | Calibrator BAN |
|-----------------|-------------|----------------|
| ADVIA IMS HbA1c | 00395488 | 08248751 |

Minimum Detectable Concentration

| Method | ADVIA IMS | RA-1000 |
|--------|-----------|---------|
| MDC | 0.61% | 17.2% |

A. Imprecision

| ADVIA IMS | | Bayer RA-1000 | |
|-----------|--------------|---------------|-------------|
| Level % | Total CV (%) | Level (%) | Total CV(%) |
| 5.71 | 5.4 | 4.6 | 3.4 |
| 8.36 | 4.7 | 8.4 | 2.6 |
| 11.17 | 4.6 | 11.2 | 2.5 |

B. Correlation (Y=ADVIA IMS, X=Comparison system)

| Specimen type | Comparison System (X) | N | Regression Equation | Syx % | R | Sample Range (%) |
|---------------|-----------------------|----|---------------------|-------|-------|------------------|
| Serum | RA-1000 | 57 | Y= 1.00 X + 0.62 | 0.33 | 0.991 | 5.09 - 17.21 |

Gabriel J. Murawski Jr.

11/5/99

C. Interfering Substances

| Interfering Substance | Interfering Sub. Conc. (mg/dL) | HbA1c Conc. (%) | Effect (% change) |
|--------------------------|--------------------------------|-----------------|-------------------|
| Bilirubin (unconjugated) | 25 | 5.21 | -1 |
| Bilirubin (conjugated) | 20 | 5.19 | -2 |
| Urea | 500 | 7.86 | +4 |
| Lipids (Triglycerides) | 1000 | 5.26 | -4 |

D. Analytical Range 0.61 to 17.2%

Date 1/15/99

Bayer Corporation, Business Group Diagnostics
Tarrytown, NY.

Gabriel J. Muraca, Jr.

Gabriel J. Muraca, Jr.
Manager Regulatory Affairs

914-524-3494 (fax 914-524-2500)

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Gentamicin Method for ADVIA® IMS**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____ (leave blank)

1. Intended Use

This in vitro method is intended to quantitatively measure gentamicin in human serum on the Bayer ADVIA® IMS systems. Measurements of gentamicin are used to aid in the diagnosis and treatment of gentamicin overdose and in monitoring serum levels of gentamicin to ensure appropriate therapy.

2. Predicate Device

| Product Name | Reagent Part # | Calibrator Part # |
|------------------------------|----------------|-------------------|
| Bayer Immuno 1 Gentamicin | T01-3154-51 | T03-2864-01 |

3. Device / Method

| Product Name | Reagent BAN | Calibrator BAN |
|----------------------|-------------|----------------|
| ADVIA IMS Gentamicin | 02543484 | 05442131 |

Minimum Detectable Concentration

| Method | ADVIA IMS | Immuno 1 |
|--------|------------|-----------|
| MDC | 0.06 µg/mL | 0.11µg/mL |

Imprecision

| ADVIA IMS | | Bayer Immuno 1 | |
|----------------|-----------------|----------------|----------------|
| Level µg/mL | Total CV (%) | Level µg/mL | Total CV(%) |
| 1.79 | 7.2 | 3.20 | 4.6 |
| 5.40 | 4.6 | 7.00 | 2.6 |
| 9.14 | 4.9 | 9.50 | 2.9 |

B. Correlation (Y=ADVIA IMS, X=Comparison system)

| Specimen type | Comparison System (X) | N | Regression Equation | Syx µg/mL | R | Sample Range µg/mL |
|---------------|-----------------------|----|---------------------|-----------|-------|--------------------|
| Serum | Immuno 1 | 54 | Y= 1.09X - 0.29 | 0.51 | 0.989 | 0.5 -11.5 |

Gabriel J. Muraca, Jr.
11/5/99

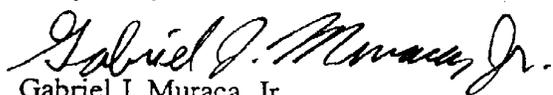
C. Interfering Substances

| Interfering Substance | Interfering Sub. Conc. (mg/dL) | Gentamicin Concentration $\mu\text{g/mL}$ | Effect (% change) |
|--------------------------|--------------------------------|---|-------------------|
| Bilirubin (unconjugated) | 25 | 4.23 | +3 |
| Bilirubin (conjugated) | 20 | 4.34 | +3 |
| Hemoglobin | 600 | 4.37 | -4 |
| Lipids (Triglycerides) | 1000 | 4.05 | +4 |

Analytical Range 0.06 to 16.0 $\mu\text{g/mL}$

Date 11/5/99

Bayer Corporation, Business Group Diagnostics
Tarrytown, NY.



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**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Magnesium method for ADVIA® IMS**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is. _____

1. Intended Use

This in vitro method is intended to quantitatively measure magnesium in human serum, plasma and urine on the Bayer ADVIA IMS. Measurements of serum magnesium are used in the diagnosis and treatment of hypomagnesemia and monitoring of patients receiving prolonged magnesium-free intravenous therapy. Measurements of urine magnesium are used to aid in the management of patients with renal dysfunction.

2. Predicate Device

| Product Name | Reagent Part # | Calibrator Part # |
|------------------|----------------|-------------------|
| Technicon CHEM 1 | T01-3269-53 | T03-1291-62 |

3. Device / Method

| Product Name | Reagent Part # | Calibrator Part # |
|-----------------|----------------|-------------------|
| Bayer ADVIA IMS | BAN 02115121 | T03-1291-62 |

A. Imprecision (Serum)

| ADVIA IMS | |
|---------------|-------------|
| Level (mg/dL) | Total CV(%) |
| 1.76 | 2.4% |
| 2.32 | 1.7% |
| 5.29 | 1.8% |

| CHEM 1 | |
|---------------|-------------|
| Level (mg/dL) | Total CV(%) |
| 1.6 | 4.1% |
| 2.8 | 2.5% |
| 3.6 | 2.3% |

B. Imprecision (Urine)

| ADVIA IMS | |
|---------------|-------------|
| Level (mg/dL) | Total CV(%) |
| 1.00 | 8.6% |
| 6.50 | 3.7% |
| 14.24 | 2.1% |

| CHEM 1 | |
|---------------|-------------|
| Level (mg/dL) | Total CV(%) |
| 1.1 | 12.6% |
| 6.5 | 2.9% |
| 14.2 | 1.4% |

Gabriel J. Munoz, Jr.
11/5/99

Correlation (Y=ADVIA IMS, X=comparison system)

| Specimen type | Comparison System (X) | N | Regression Equation | Syx (mg/dL) | R | Sample Range (mg/dL) |
|---------------|-----------------------|----|---------------------|-------------|-------|----------------------|
| Serum | CHEM 1 | 44 | $Y=0.97X+0.06$ | 0.16 | 0.998 | 0.2 - 8.05 |
| Urine | CHEM 1 | 48 | $1.02X-0.24$ | 0.34 | 0.998 | 1.4 - 25.0 |

Plasma (Y) vs. Serum (X) Comparison

| | Plasma mg/dL | Serum mg/dL | N | Difference (%) | Sample Range mg/dL |
|---------------|--------------|-------------|----|----------------|--------------------|
| concentration | 1.97 | 1.97 | 60 | 0 | 1.63 - 2.3 |
| Within-run CV | 8.92 | 9.73 | | | |

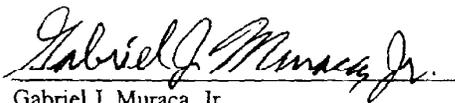
Interfering Substances

| Source | Interfering Substance | Interfering Sub. Conc. (mg/dL) | Magnesium Conc (mg/dL) | Effect (% change) |
|--------|--------------------------|--------------------------------|------------------------|-------------------|
| Serum | Bilirubin (unconjugated) | 25 | 2.23 | -1 |
| Serum | Bilirubin (conjugated) | 25 | 1.98 | 0 |
| Serum | Hemoglobin | 1000 | 2.21 | +8 |
| Serum | Lipids (Triglycerides) | 500 | 2.12 | -1 |
| Serum | Calcium | 20 | 2.08 | -3 |
| Urine | Ascorbate | 200 | 5.92 | +2 |
| Urine | Salicylate | 500 | 5.67 | +2 |
| Urine | Acetaminophen | 50 | 6.02 | -7 |

Analytical Range

Serum/Plasma: 0 to 8.0 mg/dL

Urine: 0 to 25 mg/dL



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 Manager Regulatory Affairs
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11/5/99
 Date

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Theophylline Method for ADVIA® IMS**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____ (leave blank)

1. Intended Use

This in vitro method is intended to quantitatively measure theophylline in human serum on the Bayer ADVIA® IMS systems. Measurements of theophylline are used to aid in the diagnosis and treatment of theophylline overdose and asthma in children and adults.

2. Predicate Device

| Product Name | Reagent Part # | Calibrator Part # |
|-------------------------------|----------------|-------------------|
| Bayer RA-1000 Theophylline | T01-1695-01 | T03-1692-01 |

3. Device / Method

| Product Name | Reagent BAN | Calibrator BAN |
|------------------------|-------------|----------------|
| ADVIA IMS Theophylline | 03246211 | 08491893 |

Minimum Detectable Concentration

| Method | ADVIA IMS | Immuno 1 |
|--------|------------|------------|
| MDC | 0.47 µg/mL | 0.40 µg/mL |

A. Imprecision

| ADVIA IMS | | Bayer RA-1000 | |
|----------------|-----------------|----------------|-----------------|
| Level µg/mL | Total CV (%) | Level µg/mL | Total CV (%) |
| 9.37 | 3.4 | 10.0 | 4.5 |
| 19.59 | 3.0 | 20.0 | 4.1 |
| 29.17 | 4.1 | 40.0 | 4.3 |

B. Correlation (Y=ADVIA IMS, X=Comparison system)

| Specimen type | Comparison System (X) | N | Regression Equation | Syx µg/mL | R | Sample Range µg/mL |
|---------------|-----------------------|----|---------------------|--------------|-------|-----------------------|
| Serum | RA-1000 | 51 | Y = 0.98 X - 0.13 | 1.37 | 0.991 | 4.1 - 39.6 |

Gabriel J. Moraw, Jr.
11/5/99

C. Interfering Substances

| Interfering Substance | Interfering Sub. Conc. (mg/dL) | Theophylline Concentration $\mu\text{g/mL}$ | Effect (% change) |
|--------------------------|--------------------------------|---|-------------------|
| Bilirubin (unconjugated) | 25 | 8.65 | +6 |
| Bilirubin (conjugated) | 15 | 9.00 | +7 |
| Hemoglobin | 600 | 9.03 | -4 |
| Lipids (Triglycerides) | 1000 | 9.01 | -6 |

Analytical Range 0.47 to 40 $\mu\text{g/mL}$

Date *11/5/99*

Bayer Corporation, Business Group Diagnostics
Tarrytown, NY.

Gabriel J. Muraca, Jr.
Gabriel J. Muraca, Jr.
Manager Regulatory Affairs

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**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Tobramycin Method for ADVIA® IMS**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____ (leave blank)

1. Intended Use

This in vitro method is intended to quantitatively measure tobramycin in human serum on the Bayer ADVIA® IMS systems. Measurements of tobramycin are used to aid in the diagnosis and treatment of tobramycin overdose and in monitoring serum levels of tobramycin to ensure appropriate therapy.

2. Predicate Device

| Product Name | Reagent Part # | Calibrator Part # |
|------------------------------|----------------|-------------------|
| Bayer Immuno 1 Tobramycin | T01-3157-51 | T03-2864-01 |

3. Device / Method

| Product Name | Reagent BAN | Calibrator BAN |
|----------------------|-------------|----------------|
| ADVIA IMS Tobramycin | 04946969 | 05442131 |

Minimum Detectable Concentration

| Method | ADVIA IMS | Immuno 1 |
|--------|------------|------------|
| MDC | 0.34 µg/mL | 0.08 µg/mL |

A. Imprecision

| ADVIA IMS | | Bayer Immuno 1 | |
|----------------|-----------------|----------------|----------------|
| Level µg/mL | Total CV (%) | Level µg/mL | Total CV(%) |
| 1.92 | 4.3 | 1.15 | 4.0 |
| 3.71 | 2.9 | 4.42 | 2.4 |
| 7.86 | 3.3 | 8.29 | 2.2 |

B. Correlation (Y=ADVIA IMS, X=Comparison system)

| Specimen type | Comparison System (X) | N | Regression Equation | Syx µg/mL | R | Sample Range µg/mL |
|---------------|-----------------------|----|---------------------|-----------|-------|--------------------|
| Serum | Immuno 1 | 69 | $Y = 0.99X - 0.05$ | 0.22 | 0.997 | 0.3-11.5 |

Gabriel J. Munoz, Jr.
11/5/99

C. Interfering Substances

| Interfering Substance | Interfering Sub. Conc. (mg/dL) | Tobramycin Concentration $\mu\text{g/mL}$ | Effect (% change) |
|--------------------------|--------------------------------|---|-------------------|
| Bilirubin (unconjugated) | 25 | 2.36 | +6 |
| Bilirubin (conjugated) | 20 | 2.46 | +3 |
| Hemoglobin | 600 | 2.44 | 0 |
| Lipids (Triglycerides) | 1000 | 2.42 | -1 |

Analytical Range 0.34 to 16.0 $\mu\text{g/mL}$

Date 11/5/99

Bayer Corporation, Business Group Diagnostics
Tarrytown, NY.



Gabriel J. Muraca, Jr.
Manager Regulatory Affairs

914-524-3494 (fax 914-524-2500)

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Uric Acid method for ADVIA[®] IMS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____

1. Intended Use

This *in vitro* diagnostic method is intended to measure Uric Acid in human serum, plasma or urine on the Bayer ADVIA IMS system

2. Predicate Device

| Product Name | Reagent Part # | Calibrator Part # |
|---|----------------|-------------------|
| Technicon CHEM 1 [®] Uric Acid | T01-1655-53 | T03-1291-62 |

3. Device / Method

| Product Name | Reagent Part # | Calibrator Part # |
|---------------------|----------------|-------------------|
| ADVIA IMS Uric Acid | 05132620 | T03-1291-62 |

A. Imprecision(SERUM)

| ADVIA IMS | | CHEM 1 | |
|---------------|-------------|---------------|-------------|
| Level (mg/dL) | Total CV(%) | Level (mg/dL) | Total CV(%) |
| 3.68 | 3.6 | 3.8 | 6.3 |
| 6.84 | 3.2 | 9.3 | 3.1 |
| 11.50 | 1.7 | 16.3 | 3.3 |

B. Imprecision(URINE)

| ADVIA IMS | | CHEM 1 | |
|---------------|-------------|---------------|-------------|
| Level (mg/dL) | Total CV(%) | Level (mg/dL) | Total CV(%) |
| 20.5 | 7.2 | N/A | N/A |
| 32.4 | 4.0 | 26.4 | 8.2 |
| 45.2 | 5.6 | 35.4 | 7.2 |

Correlation (Y=ADVIA IMS, X=comparison system)

| Specimen type | Comparison System (X) | N | Regression Equation | Syx (mg/dL) | r | Sample Range (mg/dL) |
|---------------------|-----------------------|----|---------------------|-------------|-------|----------------------|
| Serum | CHEM 1 | 60 | Y = 0.96X + 0.14 | 0.98 | 0.973 | 1.5 - 19.7 mg/dL |
| Plasma(y), Serum(x) | ADVIA IMS | 60 | Y = 1.01X + 0.06 | 0.16 | 0.989 | 2.9-8.0 mg/dL |
| Urine | CHEM 1 | 51 | Y = 1.11X - 3.1 | 4.0 | 0.992 | 1.0 - 123.0 mg/dL |

Gabriel J. Munoz, Jr.
11/5/99

Interfering Substances(In Serum)

| Interfering Substance | Interfering Sub. Conc. (mg/dL) | Uric Acid Conc. (mg/dL) | Effect (% change) |
|------------------------|--------------------------------|-------------------------|-------------------|
| Bilirubin | 20 | 3.8 | -7.9 |
| Hemoglobin | 500 | 3.8 | +15.8 |
| Lipids (Triglycerides) | 500 | 3.8 | +36.7 |

Interfering Substances(In Urine)

| Interfering Substance | Interfering Sub. Conc. (mg/dL) | Uric Acid Conc. (mg/dL) | Effect (% change) |
|-----------------------|--------------------------------|-------------------------|-------------------|
| Acetaminophen | 500 | 18.4 | +1.1 |
| Ascorbic Acid | 200 | 18.4 | +10.9 |
| Salicylate | 500 | 18.4 | -2.7 |

Analytical Range

Serum/Plasma: 0 to 23 mg/dL
Urine: 0 to 200 mg/dL

Daniel J. Murray, Jr.

11/5/99



APR 10 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Gabriel J. Muraca, Jr.
Manager Regulatory Affairs
Bayer Corporation
Business Group Diagnostic
511 Benedict Avenue
Tarrytown, New York 10591-5097

Re: K993867
Trade Name: Bayer ADVIA® IMS System
Regulatory Class: II
Product Code: CIG, JGJ, KLS, KNK, LCD, LCP, LDO
Dated: February 21, 2000
Received: February 29, 2000

Dear Mr. Muraca:

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 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). 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 requirements, 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

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 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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style.

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): K493867

Device Name: **Direct Bilirubin (DBIL)**

Indications For Use:

The Bayer Advia IMS Direct Bilirubin assay is an *in vitro* diagnostic device intended to measure conjugated bilirubin in human serum or plasma. Measurements of direct or total bilirubin organic compounds formed during the normal and abnormal destruction of red blood cells, are used in the diagnosis, monitoring and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gall bladder disorders.

Device Name: **Hemoglobin A1c (HbA1c)**

Indications For Use:

The Bayer Advia IMS Hemoglobin A1c (HbA1c) method is an *in vitro* diagnostic device intended to measure Hemoglobin A1c, a diabetes marker, in human blood. Measurements of HbA1c can be used for monitoring the long term care of persons with diabetes. The HbA1c and total hemoglobin (THb) values generated as part of the HbA1c assay are intended for use in the calculation of the HbA1c/THb ratio, and must not be used individually for diagnostic purposes.

Megan Coogler
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K493867

(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 Formal 1-2-96

510(k) Number (if known):

Device Name: **Gentamicin**

Indications For Use:

The Bayer Advia IMS Gentamicin assay is an *in vitro* diagnostic device intended to measure gentamicin, an antibiotic drug, in human serum. Measurements of gentamicin are used as an aid in the diagnosis and treatment of gentamicin overdose and in monitoring therapeutic levels of gentamicin to ensure appropriate therapy.

Device Name: **Magnesium (MG)**

Indications For Use:

The Bayer Advia IMS Magnesium method is an *in vitro* diagnostic device intended to measure magnesium in human serum, plasma or urine. Measurements of magnesium are used in the diagnosis and treatment of hypomagnesemia, hypermagnesemia and monitoring of patients receiving prolonged magnesium-free intravenous therapy.

Device Name: **Theophylline (THEO)**

Indications For Use:

The Bayer Advia IMS Theophylline assay is an *in vitro* diagnostic device intended to measure theophylline in human serum. Measurements of theophylline are used as an aid in the diagnosis and treatment theophylline overdose and in monitoring therapeutic levels of theophylline to ensure appropriate therapy.

(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

Sean Coyle
(Division Sign-Off)
Division of Clinical Laboratory Devices

Optional Form 1-2-96

510(k) Number K993867

510(k) Number (if known):

Device Name: **Tobramycin (TOBRA)**

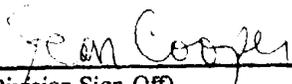
Indications For Use:

The Bayer Advia IMS Tobramycin assay is an *in vitro* diagnostic device intended to quantitatively measure tobramycin, an antibiotic drug, human serum. Measurements of tobramycin are used in the diagnosis and treatment of tobramycin overdose and in monitoring therapeutic levels of tobramycin to ensure appropriate therapy.

Device Name: **Uric Acid (UA)**

Indications For Use:

The Bayer Advia IMS Uric Acid (UA) method is an *in vitro* diagnostic device intended to measure uric acid in human serum, plasma, and urine. Such measurements are used as an aid in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, and of patients receiving cytotoxic drugs.



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K99256-7

(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 Form 1-2-96