K101456

SEP 0 8 2010

## 510(k) Summary – Calibrator for Automated Systems (C.f.a.s.) and C.f.a.s. CK-MB

**Introduction**

Roche Diagnostics Corporation hereby submits this 510(k) to provide notification of modifications to our Calibrator for automated systems (C.f.a.s.) and C.f.a.s. CK-MB.

1. C.f.a.s. was originally cleared for use in K990460, then modified in K033501 and K062319.
2. C.f.a.s. CK-MB was originally cleared for use in K003158.

Modifications to these devices include changing common source materials for three analytes

- Human recombinant Gamma-glutamyltransferase (γGT) will replace porcine kidney γGT in C.f.a.s.
- Human recombinant Aspartate aminotransferase (AST) will replace porcine heart AST in C.f.a.s.
- Human recombinant Creatine Kinase Isoenzyme MB (CK-MB) will replace porcine brain Creatine Kinase Isoenzyme BB (CK-BB) in C.f.a.s. CK-MB.

**Submitter name, address, contact**

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Date prepared: June 16, 2010

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## 510(k) Summary – Calibrator for Automated Systems (C.f.a.s.) and C.f.a.s. CK-MB, Continued

**Device names**

Proprietary names:

1. Roche Diagnostics Calibrator for automated systems
2. Roche Diagnostics Calibrator for automated systems CK-MB

Common names:

1. C.f.a.s.
2. C.f.a.s. CK-MB

Classification names:

1. Calibrator, Multi-analyte mixture
2. Calibrator, Secondary

Product Codes:

1. JIX
2. JIT

**Device description**

1. C.f.a.s. is for use in the calibration for automated Roche methods on Roche chemistry analyzers as specified in the enclosed value sheet. It is a lyophilized calibrator based on human serum.
2. C.f.a.s. CK-MB is for use in the calibration of Roche methods for the quantitative determination of the MB Isoenzyme of Creatine kinase on automated clinical chemistry analyzers. It is a lyophilized calibrator based on bovine serum albumin.

**Intended use**

1. Calibrator for automated systems (C.f.a.s.) is for use in the calibration for automated Roche methods on Roche chemistry analyzers as specified in the value sheets.
2. C.f.a.s. (Calibrator for automated systems) CK-MB is for use in the calibration of Roche methods for the quantitative determination of CK-MB on Roche clinical chemistry analyzers as specified in the value sheets.

**Predicate devices**

We claim substantial equivalence to the following currently marketed devices.

1. . Calibrator for automated systems cleared in K062319.
2. Calibrator for automated systems CK-MB cleared in K003158.

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## 510(k) Summary – Calibrator for Automated Systems (C.f.a.s.) and C.f.a.s. CK-MB, Continued

**Substantial equivalence**

Tables 1 and 2 compare the features of the modified devices with their predicate devices. The first is a comparison of C.f.a.s.; the second is a comparison for C.f.a.s. CK-MB.

Table 1: Comparison of C.f.a.s.

| Feature | C.f.a.s (Modified Device) | C.f.a.s. K062319 (Predicate Device) |
|---|---|---|
| Intended Use | Calibrator for automated systems (C.f.a.s.) is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the value sheets. | Calibrator for automated systems (C.f.a.s) is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the lot specific value sheet. |
| Format | Lyophilized | Same |
| Stability | Lyophilized calibrator<br>• 2 to 8 °C until expiration date<br><br>Reconstituted calibrator<br>• 15 to 25 °C for 8 hours<br>• 2 to 8 °C for 2 days<br>• -15 to -25 °C for 4 weeks (when frozen once)<br><br>Total Bilirubin in reconstituted calibrator when stored protected from light<br>• 15 to 25 °C for 6 hours<br>• 2 to 8 °C for 1 day<br>• -15 to -25 °C for 2 weeks (when frozen once)<br><br>Direct Bilirubin in reconstituted calibrator when stored protected from light<br>• 15 to 25 °C for 3 hours<br>• 2 to 8 °C for 8 hours<br>• -15 to -25 °C for 2 weeks (when frozen once) | Same |
| Levels | Single level | Same |
| Reagent Composition | Lyophilized human serum with chemical additives and material of biological origin | Same |

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**Substantial equivalence** (continued)

Table 1, continued…

| Feature | C.f.a.s (Modified Device) | C.f.a.s. K062319 (Predicate Device) |
|---|---|---|
| Traceability | Traceability for each constituent is described in the reagent system instructions for use.<br><br>Additional Reference Materials<br>1. SRM 909b and SRM 956 for Calcium<br>2. SRM 929 and SRM 956 for Magnesium<br>3. SRM 914 and SRM 967 for Creatinine Jaffe<br>4. SRM 909b (IDMS) and SRM 967 for Creatinine Plus<br>5. SRM 909b (IDMS) and SRM 1951 for Triglycerides GB<br><br>Reference Material Name Changes<br>1. ERM DA470k for Albumin Plus<br>2. Primary Reference Material – USP for Salicylate<br><br>Reference Method Publication Update<br>1. IFCC (2002), Manual for ALT<br>2. IFCC (2002), Manual for AST<br>3. IFCC (2002), Manual for CK<br>4. IFCC (2002), Manual for LD | Same<br><br>Reference Materials<br>1. SRM 909b for Calcium<br>2. SRM 929 for Magnesium<br>3. SRM 914 for Creatinine Jaffe<br>4. SRM 909b (IDMS) for Creatinine Plus<br>5. SRM 909b (IDMS) for Triglycerides GB<br><br>Reference Material Names<br>1. CRM 470 for Albumin Plus<br>2. Primary Reference Material for Salicylate<br><br>Reference Method Publications<br>1. IFCC (1985), Manual for ALT<br>2. IFCC (1985), Manual for AST<br>3. IFCC (1991), Manual for CK<br>4. IFCC (1994), Manual for LD |
| Value Assignment | Values to new lots are assigned by running them as samples after calibrating the system with a previously assigned C.f.a.s. lot. Values are verified by using reference material, Master lot C.f.a.s., and previously assigned lots of C.f.a.s. | Same |
| Source Material | • Human recombinant γGT<br>• Human recombinant AST | • Porcine kidney γGT<br>• Porcine heart AST |

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## 510(k) Summary – Calibrator for Automated Systems (C.f.a.s.) and C.f.a.s. CK-MB, Continued

Table 2: Comparison of C.f.a.s. CK-MB

| Feature | C.f.a.s. CK-MB (Modified Device) | C.f.a.s. CK-MB K003158 (Predicate Device) |
|---|---|---|
| Intended Use | C.f.a.s. (Calibrator for automated systems) CK-MB is for use in the calibration of Roche methods for the quantitative determination of CK-MB on Roche clinical chemistry analyzers as specified in the value sheets. | C.f.a.s. (Calibrator for automated systems) CK-MB is for use in the calibration of Roche methods for the quantitative determination of CK-MB on automated clinical chemistry analyzers. |
| Format | Lyophilized | Same |
| Stability | Lyophilized calibrator<br>• 2 to 8 °C until expiration date<br><br>Reconstituted calibrator<br>• 15 to 25 °C for 24 hours<br>• 2 to 8 °C for 2 days<br>• -15 to -25 °C for 4 weeks (when frozen once) | Lyophilized calibrator<br>• same<br><br>Reconstituted calibrator<br>• 15 to 25 °C for 24 hours<br>• 2 to 8 °C for 2 days<br>• -20 °C for 1 month (when frozen once) |
| Levels | Single level | Same |
| Reagent Composition | Lyophilized calibrator based on bovine serum albumin with chemical additives and material of biological origin. | Same |
| Traceability | Traceability for each constituent is described in the reagent system instructions for use. | Same |
| Value Assignment | Values to new lots are assigned by running them as samples after calibrating the system with a previously assigned C.f.a.s. CK-MB lot. Values are verified by using reference material, Master lot C.f.a.s CK-MB, and previously assigned lots of C.f.a.s. CK-MB. | Same |
| Source material | • Human recombinant CK-MB<br>• Human CK-MM | • Porcine brain CK-BB<br>• Human CK-MM |

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**Constituents** Tables 3 and 4 catalog the constituent analytes and their biological source for both the modified and predicate devices. Table 3 summarizes C.f.a.s., a multi-analyte calibrator. For the modified C.f.a.s., the source material changes for two analytes, AST and γGT.

Table 3: Constituents of C.f.a.s.

| C.f.a.s (Modified Device) | | C.f.a.s. K062319 (Predicate Device) | |
|---|---|---|---|
| **Analyte** | **Source** | **Analyte** | **Source** |
| ALT/ALAT | Porcine heart | ALT/ALAT | Same |
| AST/ASAT | *Human, recombinant* | AST/ASAT | *Porcine heart* |
| Albumin | Bovine plasma | Albumin | Same |
| Alkaline phosphatase | Human placenta (recombinant) | Alkaline phosphatase | Same |
| Amylase, total | Porcine pancreas | Amylase, total | Same |
| Amylase, pancreatic | Porcine pancreas | Amylase, pancreatic | Same |
| Bilirubin, direct | Endogenous and/or chemical additive | Bilirubin, direct | Same |
| Bilirubin, total | Endogenous and/or chemical additive | Bilirubin, total | Same |
| Calcium | Endogenous and/or chemical additive | Calcium | Same |
| Cholesterol | Bovine plasma | Cholesterol | Same |
| Cholinesterase | Human serum | Cholinesterase | Same |
| Creatine kinase | Rabbit muscle | Creatine kinase | Same |
| Creatinine | Endogenous and/or chemical additive | Creatinine | Same |
| γGT | *Human, recombinant* | γGT | *Porcine kidney* |
| Glucose | Endogenous and/or chemical additive | Glucose | Same |
| Iron | Endogenous and/or chemical additive | Iron | Same |
| Lactate | Endogenous and/or chemical additive | Lactate | Same |
| LD (LDH) | Porcine heart | LD (LDH) | Same |
| Lipase | Human pancreas (recombinant) | Lipase | Same |
| Lithium | Chemical additive | N/A[1] | |
| Magnesium | Endogenous and/or chemical additive | Magnesium | Same |
| Phosphorus | Endogenous and/or chemical additive | Phosphorus | Same |
| Salicylate | Chemical additive | Salicylate | Same |
| Total Protein | Endogenous and/or chemical additive | Total Protein | Same |
| Triglycerides | Chicken egg yolk | Triglycerides | Same |
| UIBC | Endogenous and/or chemical additive | UIBC | Same |
| Urea/BUN | Endogenous and/or chemical additive | Urea | Same |
| Uric Acid | Endogenous and/or chemical additive | Uric Acid | Same |

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[1] C.f.a.s. was cleared as the calibrator in the Lithium test system in K063684. The source for lithium is the same.

## 510(k) Summary – Calibrator for Automated Systems (C.f.a.s.) and C.f.a.s. CK-MB, Continued

**Constituents** (continued)

Table 4 summarizes C.f.a.s CK-MB. It is a single analyte calibrator that contains two Creatine kinase Isoenzyme sources; CK-MB Isoenzyme is the detected analyte in the test system. For the modified C.f.a.s. CK-MB, the source material changes for one of the two CK Isoenzyme biological additives.

Table 4: Constituents of C.f.a.s. CK-MB

| **C.f.a.s. CK-MB (Modified Device)** | | **C.f.a.s. CK-MB K003158 (Predicate Device)** | |
|---|---|---|---|
| **Analyte** | **Source** | **Analyte** | **Source** |
| CK-MB Isoenzyme | • *Human recombinant CK-MB Isoenzyme*<br>• Human CK-MM Isoenzyme | CK-MB Isoenzyme | • *Porcine brain CK-BB Isoenzyme*<br>• Human CK-MM Isoenzyme |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Roche Diagnostics
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Indianapolis, IN, 46250-0416

SEP 8 2010

Re: k101456
Trade Names: Calibrator for automated systems (C.f.a.s.)
Calibrator for automated systems CK-MB (C.f.a.s. CK-MB)
Regulation Number: 21 CFR §862.1150
Regulation Name: Calibrator, Multi-Analyte Mixture and Calibrator, Secondary
Regulatory Class: Class II
Product Codes: JIX, JIT
Dated: August 23, 2010
Received: August 24, 2010

Dear Mr. Hollandbeck:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

# Indications for Use Form

K101456

SEP 0 8 2010

510(k) Number (if known): K101456

Device Name:

Calibrator for automated systems (C.f.a.s.)

Indications for Use:

Calibrator for automated systems (C.f.a.s) is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the value sheets.

Prescription Use ___x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101456

# Indications for Use Form

510(k) Number (if known): K101456

K101456
SEP 08 2010

Device Name:

Calibrator for automated systems (C.f.a.s.) CK-MB

Indications for Use:

C.f.a.s. (Calibrator for automated systems) CK-MB is for use in the calibration of Roche methods for the quantitative determination of CK-MB on Roche clinical chemistry analyzers as specified in the value sheets.

Prescription Use ___x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101456