510(k) Summary of Safety and Effectiveness
for the ADVIA® Chemistry Fructosamine (FRUC) Assay and Calibrator

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

A. 510(k) Number: k131307

B. Date of Preparation: May 3, 2013

C. Proprietary and Established Names:
   ADVIA® Chemistry Fructosamine (FRUC) Assay
   ADVIA® Chemistry Fructosamine Calibrator

D. Applicant
   Contact: Kira Gordon
            Sr. Regulatory Technical Specialist
   Address: Siemens Healthcare Diagnostics, Inc
            511 Benedict Ave
            Tarrytown, NY 10591
   Phone: (914) 524-2996
           (914) 524-3579 (fax)

E. Regulatory Information:
   Reagent
   1. Regulation section: 21 CFR §864.7470, Glycosylated hemoglobin assay
   2. Classification: Class II
   3. Product Code: LCP
   4. Panel: Hematology (81)

   Calibrator
   1. Regulation section: 21 CFR §862.1150, Calibrator, secondary
   2. Classification: Class II
   3. Product Code: JIT
   4. Panel: Clinical Chemistry (75)

F. Predicate Device:
   Reagents:
   1. Device Name:
Diazyme Glycated Serum Protein Assay
2. Common Name:
   Diazyme Glycated Serum Protein Assay
3. 510(k) Number:
k042193
4. Manufacturer:
   Diazyme Laboratories

Calibrators:
1. Device Name:
   Randox Fructosamine Calibrator
2. Common Name:
   Randox Fructosamine Calibrator
3. 510(k) Number:
k023763
4. Manufacturer:
   Randox Laboratories, Ltd.

G. Intended Use and Indication for Use:

ADVIA Chemistry Fructosamine (FRUC) Assay
For in vitro diagnostic use in the quantitative measurement of glycated protein (fructosamine) in human serum or plasma on the ADVIA® Chemistry systems. Measurement of fructosamine is representative of blood glucose levels over the preceding 2-3 weeks, and is useful for monitoring diabetic patients.

ADVIA Chemistry Fructosamine Calibrator
For in vitro diagnostic use in the calibration of the ADVIA® Chemistry Fructosamine (FRUC) assay on ADVIA Chemistry systems.

H. Device Description:
The ADVIA® Chemistry Fructosamine reagents are ready-to-use liquid packaged for use on ADVIA® 1650 Chemistry system. The reagents are supplied as 100 tests/wedge, with two (2) wedges in each kit.
- Reagent 1 (R1) contains Tris Buffer (0.2 mol/L, pH 8.0), Proteinase-K (≥ 1 kU/mL) 4-Aminoantipyrine (5 mmol/L) and Stabilizers.
- Reagent 2 (R2) contains Tris Buffer (0.2 mol/L, pH 8.65), Fructosaminase (≥ 0.5 kU/mL), Peroxidase (horseradish) (0.5 kU/mL) N-ethyl-N-sulphohydroxypropyl-m-toluidine (TOOS) (10 mmol/L) and Stabilizers.
The ADVIA® Chemistry Fructosamine Calibrator is a single analyte and single level calibrator. It is lyophilized human serum containing pure fructosamine antigen. There are three (3) vials in each kit. Each vial contains 0.08g. The volume per vial (after reconstitution with deionized water) is 1.0 mL.

I. Test Principle:
In the ADVIA® Chemistry Fructosamine Assay, Reagent 1 contains proteinase K, which digests the glycated protein to yield glycated protein fragments. Fructosaminase in Reagent 2
oxidizes the ketoamine bond of the glycated protein fragments. As a result hydrogen peroxide is released and it is involved in a colorimetric Trinder end-point reaction. The amount of color developed and measured at 596 nm is proportional to the concentration of glycated protein in the sample.

J. Substantial Equivalence Information:
1. Predicate device name:
   Reagent: Diazyme Glycated Serum Protein Assay;
2. Calibrator: Randox Fructosamine Calibrator
   Predicate K number:
3. Reagent: k042193
   Calibrator: k023763

Comparison with predicate:

<table>
<thead>
<tr>
<th>Item</th>
<th>NEW DEVICE:</th>
<th>PREDICATE DEVICE:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ADVIA® Chemistry Fructosamine (FRUC) Assay</td>
<td>Diazyme Glycated Serum Protein Assay</td>
</tr>
<tr>
<td>Intended Use/Indications for Use</td>
<td>For <em>in vitro</em> diagnostic use in the quantitative measurement of glycated protein (fructosamine) in human serum or plasma on the ADVIA® Chemistry systems. Measurement of fructosamine is representative of blood glucose levels over the preceding 2-3 weeks, and is useful for monitoring diabetic patients.</td>
<td>Same (for the quantitative determination of glycated serum proteins (GSP; glycated albumin; fructosamine). The measurement of glycated serum proteins is useful for monitoring diabetic patients.</td>
</tr>
<tr>
<td>Instrument used</td>
<td>ADVIA® 1650 Chemistry system</td>
<td>Clinical Chemistry analyzer</td>
</tr>
<tr>
<td>Measurement</td>
<td>Quantitative</td>
<td>Same</td>
</tr>
<tr>
<td>Specimen types</td>
<td>Human Serum and plasma (Lithium heparin, potassium EDTA)</td>
<td>Serum</td>
</tr>
<tr>
<td>Reference range</td>
<td>122-236 μmol/L</td>
<td>Same</td>
</tr>
<tr>
<td>Format</td>
<td>Liquid</td>
<td>Same</td>
</tr>
<tr>
<td>Analytical Range</td>
<td>30-1000 μmol/L</td>
<td>21-1354 μmol/L</td>
</tr>
<tr>
<td>Assay Principle/Methodology</td>
<td>Enzymatic reaction</td>
<td>Same</td>
</tr>
</tbody>
</table>

Calibrator:

<table>
<thead>
<tr>
<th>Item</th>
<th>NEW DEVICE:</th>
<th>PREDICATE DEVICE:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ADVIA® Chemistry Fructosamine Calibrator</td>
<td>Randox Fructosamine Calibrator</td>
</tr>
<tr>
<td>Intended Use</td>
<td>For <em>in vitro</em> diagnostic use in the calibration of the ADVIA® Chemistry</td>
<td>Same</td>
</tr>
</tbody>
</table>

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Fructosamine (FRUC) assay on ADVIA® Chemistry systems.

<table>
<thead>
<tr>
<th>Form</th>
<th>Lyophilized</th>
<th>Same</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analyte source</td>
<td>Derived from human source</td>
<td>Same</td>
</tr>
<tr>
<td>Levels</td>
<td>Single</td>
<td>Same</td>
</tr>
<tr>
<td>Fill Volume</td>
<td>0.08 g → 1.0 mL reconstituted</td>
<td>Same</td>
</tr>
<tr>
<td>Storage</td>
<td>2–8°C</td>
<td>Same</td>
</tr>
</tbody>
</table>

K. Standard/Guidance Document Reference


L. Performance Characteristics

The following data represent typical performance for the ADVIA® Chemistry Fructosamine Assay and were collected on ADVIA® 1650 Chemistry system. Substantial equivalence was demonstrated by testing several performance characteristics including imprecision, linearity/assay reportable range, limit of detection, method comparison and analytical specificity. All of the evaluation studies gave acceptable results when compared to the predicate device. These studies support that the ADVIA® Chemistry Fructosamine Assay and ADVIA® Chemistry Fructosamine Calibrator when tested on the ADVIA® 1650 Chemistry system are substantially equivalent to the Diazyme Glycated Serum Protein Assay and Randox Fructosamine Calibrator that are currently marketed.

I. Imprecision

Within-Run and Total Precision were established by assaying three samples. Each sample was assayed 2 replicates per run, 2 runs per day, for at least 20 days. Precision estimates were computed according to CLSI document EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline.

<table>
<thead>
<tr>
<th>Sample</th>
<th>N</th>
<th>Mean (µmol/L)</th>
<th>Within Run</th>
<th>Between Run</th>
<th>Between Day</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>SD</td>
<td>CV</td>
<td>SD</td>
<td>CV</td>
</tr>
<tr>
<td>Serum Pool</td>
<td>80</td>
<td>39</td>
<td>1.1</td>
<td>2.8</td>
<td>0.8</td>
<td>1.9</td>
</tr>
<tr>
<td>Serum Pool</td>
<td>80</td>
<td>70</td>
<td>0.5</td>
<td>0.7</td>
<td>1.2</td>
<td>1.7</td>
</tr>
<tr>
<td>Serum Pool</td>
<td>80</td>
<td>126</td>
<td>0.7</td>
<td>0.5</td>
<td>1.5</td>
<td>1.2</td>
</tr>
<tr>
<td>Serum Control</td>
<td>80</td>
<td>150</td>
<td>0.5</td>
<td>0.3</td>
<td>1.1</td>
<td>0.7</td>
</tr>
<tr>
<td>Serum Pool</td>
<td>80</td>
<td>273</td>
<td>0.9</td>
<td>0.3</td>
<td>1.9</td>
<td>0.7</td>
</tr>
<tr>
<td>Serum Control</td>
<td>80</td>
<td>429</td>
<td>1.1</td>
<td>0.3</td>
<td>2.2</td>
<td>0.5</td>
</tr>
<tr>
<td>Serum Pool</td>
<td>80</td>
<td>540</td>
<td>1.3</td>
<td>0.2</td>
<td>3.2</td>
<td>0.6</td>
</tr>
<tr>
<td>Serum Pool</td>
<td>80</td>
<td>731</td>
<td>1.9</td>
<td>0.3</td>
<td>1.9</td>
<td>0.3</td>
</tr>
</tbody>
</table>

II. Linearity/assay reportable range

Linearity was assessed by assaying equally spaced dilutions across the measuring range. The low end of the assay range is calculated based on the Limit of Quantitation. The high
end of the assay range is based on the linearity calculation. The ADVIA® Chemistry
Fructosamine Assay on ADVIA® 1650 Chemistry system is linear from 30–1000 μmol/L
with a deviation from linearity of ≤ 10%.
Results of the linear regression equation are as follows:
Observed FRUC (μmol/L) = 0.995 * Expected FRUC (μmol/L) + 4.12, r = 1.000

III. Limit of detection
The ADVIA® Chemistry Fructosamine Assay estimations of the Limit of Blank (LoB),
Limit of Detection (LoD) and Limit of Quantitation (LoQ) were performed according to
CLSI document EP17-A2, Evaluation of Detection Capability for Clinical Laboratory
Measurement Procedures; Approved Guideline—Second Edition using several serum pools
with fructosamine concentration and 160 replicates of blank ("zero") serum pool.
The Limit of Blank (LoB) is the highest measurement result that is likely to be observed on
a blank sample. The LoB for the ADVIA® Chemistry Fructosamine Assay is
15 μmol/L on ADVIA® 1650 Chemistry system.
The Limit of Detection (LoD) is the smallest amount that this assay can reliably detect to
determine presence or absence of an analyte. The LoD for the ADVIA® Chemistry
Fructosamine Assay is 21 μmol/L on ADVIA® 1650 Chemistry system.
LoB and LoD values are determined with proportions of false positives (α) less than 5%
and false negatives (β) less than 5%, based on 320 determinations with 160 blank and 160
low level sample replicates for the ADVIA® 1650 Chemistry system.
The Limit of Quantitation (LoQ) is based on 160 determinations and a total error goal of
30.0% calculated using the Westgard model. The LoQ for the ADVIA® Chemistry
Fructosamine Assay is 30 μmol/L on ADVIA® 1650 Chemistry system.

IV. Method comparison with predicate device:
The performance of the ADVIA® Chemistry Fructosamine Assay on ADVIA® 1650
Chemistry system (y) was compared with the performance of Diazyme Glycated Serum
Protein Assay on Hitachi 717 (x).
One hundred and thirteen (113) serum samples were tested. Three (3) samples were not
included in calculations being out if the assay range. The sample results ranged from 47–
995 μmol/L fructosamine (x), and gave a correlation coefficient (r) of 0.99. The ADVIA®
Chemistry Fructosamine assay result was calculated using least squares linear regression
(first replicate) is as follows:

<table>
<thead>
<tr>
<th>Regression Equation</th>
<th>Slope (95% CI)</th>
<th>Intercept (95% CI)</th>
<th>r</th>
<th>Sample Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>y = 0.99x - 13.1 μmol/L</td>
<td>0.99 – 1.00</td>
<td>-17.2 – -9.0</td>
<td>0.99</td>
<td>47 - 995 μmol/L</td>
</tr>
</tbody>
</table>
V. Matrix comparison
The performance of the plasma samples (y) on ADVIA® Chemistry Fructosamine Assay on was compared with the performance of serum samples (x) on ADVIA® 1650 Chemistry system.
One hundred and fifty two (152) Lithium Heparin plasma samples and one hundred twenty eight (128) potassium EDTA plasma samples were tested vs. serum; the sample results ranged from 38–940 μmol/L fructosamine (x). The ADVIA® Chemistry Fructosamine Assay result calculated using least squares linear regression (first replicate) is as follows:

<table>
<thead>
<tr>
<th>Matrix</th>
<th>Regression Equation</th>
<th>Slope (95% CI)</th>
<th>Intercept (95% CI)</th>
<th>r</th>
<th>Sample Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lithium Heparin (Plasma)</td>
<td>$y = 1.00x + 3.5$</td>
<td>0.98 to 1.02</td>
<td>-2.1 to 9.0</td>
<td>0.995</td>
<td>38 – 940 μmol/L</td>
</tr>
<tr>
<td>Potassium EDTA (Plasma)</td>
<td>$y = 1.00x - 4.6$</td>
<td>0.98 to 1.02</td>
<td>-11.2 to 2.0</td>
<td>0.994</td>
<td>38 – 940 μmol/L</td>
</tr>
</tbody>
</table>

VI. Analytical specificity
Interferences from various substances (see table below) were evaluated using a significance criterion of >10% bias. Bias is the difference in the results between the control sample (without the interferent) and the test sample (contains the interferent) expressed in percent. Bias exceeding 10% is considered interference.

<table>
<thead>
<tr>
<th>Interferent</th>
<th>Interferent Level</th>
<th>Fructosamine Sample Concentration</th>
<th>Interference*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilirubin (conjugated)</td>
<td>5 mg/dL (86 μmol/L)</td>
<td>165 μmol/L</td>
<td>NSI</td>
</tr>
<tr>
<td></td>
<td>10 mg/dL (171 μmol/L)</td>
<td>165 μmol/L</td>
<td>-18.3%</td>
</tr>
<tr>
<td></td>
<td>5 mg/dL (86 μmol/L)</td>
<td>210 μmol/L</td>
<td>NSI</td>
</tr>
<tr>
<td></td>
<td>10 mg/dL (171 μmol/L)</td>
<td>254 μmol/L</td>
<td>NSI</td>
</tr>
<tr>
<td>Bilirubin (unconjugated)</td>
<td>5 mg/dL (86 μmol/L)</td>
<td>165 μmol/L</td>
<td>NSI</td>
</tr>
<tr>
<td></td>
<td>10 mg/dL (171 μmol/L)</td>
<td>165 μmol/L</td>
<td>-16.3%</td>
</tr>
<tr>
<td></td>
<td>10 mg/dL (171 μmol/L)</td>
<td>264 μmol/L</td>
<td>NSI</td>
</tr>
<tr>
<td></td>
<td>15 mg/dL (257 μmol/L)</td>
<td>264 μmol/L</td>
<td>-12.4%</td>
</tr>
<tr>
<td>Hematocrit</td>
<td>750 mg/dL (13.5 g/dL)</td>
<td>154 μmol/L</td>
<td>NSI</td>
</tr>
<tr>
<td></td>
<td>500 mg/dL (9.0 g/dL)</td>
<td>154 μmol/L</td>
<td>-11.3%</td>
</tr>
<tr>
<td></td>
<td>750 mg/dL (7.5 g/dL)</td>
<td>253 μmol/L</td>
<td>NSI</td>
</tr>
<tr>
<td></td>
<td>1000 mg/dL (10.0 g/dL)</td>
<td>253 μmol/L</td>
<td>-13.7%</td>
</tr>
<tr>
<td>Uremia</td>
<td>1000 mg/dL (11.3 mmol/L)</td>
<td>156 μmol/L</td>
<td>NSI</td>
</tr>
<tr>
<td></td>
<td>1000 mg/dL (11.3 mmol/L)</td>
<td>256 μmol/L</td>
<td>NSI</td>
</tr>
<tr>
<td>Acetate Acid</td>
<td>10 mg/dL (168 μmol/L)</td>
<td>156 μmol/L</td>
<td>NSI</td>
</tr>
<tr>
<td></td>
<td>15 mg/dL (252 μmol/L)</td>
<td>156 μmol/L</td>
<td>NSI</td>
</tr>
<tr>
<td></td>
<td>20 mg/dL (1136 μmol/L)</td>
<td>250 μmol/L</td>
<td>NSI</td>
</tr>
<tr>
<td>Glucose</td>
<td>2000 mg/dL (135 mmol/L)</td>
<td>154 μmol/L</td>
<td>NSI</td>
</tr>
<tr>
<td></td>
<td>2800 mg/dL (155 mmol/L)</td>
<td>251 μmol/L</td>
<td>NSI</td>
</tr>
<tr>
<td>Lactic Acid</td>
<td>50 mg/dL (2975 μmol/L)</td>
<td>159 μmol/L</td>
<td>NSI</td>
</tr>
<tr>
<td></td>
<td>50 mg/dL (2975 μmol/L)</td>
<td>251 μmol/L</td>
<td>NSI</td>
</tr>
<tr>
<td>Albumin</td>
<td>6.1 g/dL (161 g/L)</td>
<td>132 μmol/L</td>
<td>NSI</td>
</tr>
<tr>
<td>Total Protein</td>
<td>0.4 g/dL (84 g/L)</td>
<td>489 μmol/L</td>
<td>NSI</td>
</tr>
</tbody>
</table>

*NSI = no significant interference. A percentage effect ≥ 10% is considered a significant interference.
VII. **Reagent and Calibrator Stability**
Reagent: for opened products, once placed on the system reagents are stable for 60 days. The shelf life of the ADVIA Chemistry Fructosamine Reagent is 12 months at 2-8°C. For unopened product, see the expiration date on the reagent carton.
Calibrator: for opened products, once the cap is removed, assigned values are stable for 28 days when recapped immediately after use and stored at 2-8°C. The shelf life of the ADVIA Chemistry Fructosamine Calibrator is 12 months at 2-8°C. For unopened product, see the expiration date on the calibrator carton.

VII. **Value Assignment**
The ADVIA Chemistry FRUC assay is traceable to an internal standard. Assigned values of the ADVIA Chemistry Fructosamine Calibrator are traceable to this standardization. The value assignment is carried out by a nested testing protocol using one lot of reagent on one ADVIA® 1650 Chemistry system with ten (10) replicates of the Master Lot and Test Lot calibrators in the same worklist. The Test Lot values are adjusted with a ratio derived from the Master Lot Calibrator assigned value (Target value) and the mean recovery of the Master Lot Calibrator values (observed) according to the following equation: Test Lot assigned value = (Master Calibrator Target value / Mean Recovery of the Master Lot Calibrator observed) * Mean Recovery of Test Lot observed.

VII. **Clinical Studies**
Not applicable.

VIII. **Clinical cut-off**
Not applicable.

M. **Conclusion**
The ADVIA® Chemistry Fructosamine Assay on ADVIA® 1650 Chemistry system is substantially equivalent in principle and in performance to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Diazyme Glycated Serum Protein Assay (k042193).

The ADVIA® Chemistry Fructosamine Calibrator on ADVIA® 1650 Chemistry system is substantially equivalent in principle and in performance to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Randox Fructosamine Calibrator (k023763).
De: K131307
Trade/Device Name: ADVIA® Chemistry Fructosamine (FRUC) Assay
AD VIA® Chemistry Fructosamine Calibrator
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: II
Product Code: LCP, JIT
Dated: December 6, 2013
Received: December 9, 2013

Dear Dr. Gordon:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.
If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact 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/MedicalDevices/ResourcesforYou/Industry/default.htm. 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure
Device Name
ADVIA® Chemistry Fructosamine (FRUC) Assay; ADVIA® Chemistry Fructosamine Calibrator

Indications for Use (Describe)
The ADVIA® Chemistry Fructosamine (FRUC) Assay

For in vitro diagnostic use in the quantitative measurement of glycated protein (fructosamine) in human serum or plasma on the ADVIA® Chemistry systems. Measurement of fructosamine is representative of blood glucose levels over the preceding 2-3 weeks, and is useful for monitoring diabetic patients.

ADVIA® Chemistry Fructosamine Calibrator

For in vitro diagnostic use in the calibration of the ADVIA® Chemistry Fructosamine (FRUC) assay on ADVIA® Chemistry systems.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)
☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Stayce Beck

FORM FDA 3881 (1/14) Page 1 of 2
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PRAStaff@fda.hhs.gov

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