A. 510(k) Number:

k110641

B. Purpose for Submission:

New device

C. Measurand:

Quality control materials for Vitamin D assays

D. Type of Test:

Quality Control Materials

E. Applicant:

Fujirebio Diagnostics, Inc.

F. Proprietary and Established Names:

Fujirebio Diagnostics Vitamin D Control

G. Regulatory Information:

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Classification</th>
<th>Regulation Section</th>
<th>Panel</th>
</tr>
</thead>
<tbody>
<tr>
<td>JJX</td>
<td>Class I, reserved</td>
<td>21 CFR 862.1660</td>
<td>Clinical Chemistry (75)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Quality Control Material</td>
<td></td>
</tr>
</tbody>
</table>

H. Intended Use:

1. Intended use(s):

Refer to indication for use below.

2. Indication(s) for use:

Fujirebio Diagnostics Vitamin D Control is intended for use as an assayed control serum to monitor the precision of laboratory testing procedures for the analysis of Vitamin D.

3. Special conditions for use statement(s):
For in vitro diagnostic use only.

Fujirebio Diagnostics Vitamin D Control is made from human source material, and therefore should be treated as potentially infectious. Each human donor unit used to manufacture this control was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV), antibody to HIB-1/HIV-2, and antibody to Treponema Pallidum (Syphilis). This product may also contain other human pathogens for which there are no approved tests. All human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

4. Special instrument requirements:

None

I. Device Description:

The Fujirebio Diagnostics Vitamin D Control is prepared from human serum, protein (bovine), purified biochemical materials, and chemicals. It also contains Proclin 300® and Gentamicin as preservatives.

The controls are provided in lyophilized form. The control levels contain Vitamin D at the corresponding target concentrations.

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Analyte Form</th>
<th>Target Concentrations (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Level 1</td>
</tr>
<tr>
<td>25 (OH) Vitamin D</td>
<td>25 (OH) D2</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>25 (OH) D3</td>
<td>10</td>
</tr>
</tbody>
</table>

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Bio-Rad Liquichek™ Specialty Immunoassay Control – 25-OH Vitamin D

2. Predicate 510(k) number(s):

   k043108

3. Comparison with predicate:

<table>
<thead>
<tr>
<th>Items</th>
<th>Fujirebio Diagnostics Vitamin D Control (Candidate Device)</th>
<th>Bio-Rad Liquichek™ Specialty Immunoassay Control – 25-OH Vitamin D (Predicate Device)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Similarity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------------</td>
<td>----------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>Intended Use</td>
<td>Same</td>
<td>For use as an assayed quality control</td>
</tr>
<tr>
<td></td>
<td></td>
<td>testing procedures for the measurement</td>
</tr>
<tr>
<td></td>
<td></td>
<td>of 25-OH Vitamin D</td>
</tr>
<tr>
<td>Analyte(s)</td>
<td>Same</td>
<td>25-OH Vitamin D</td>
</tr>
<tr>
<td>Levels of Controls</td>
<td>Same</td>
<td>3</td>
</tr>
<tr>
<td>Matrix</td>
<td>Same</td>
<td>Human Serum with additives</td>
</tr>
</tbody>
</table>

| Differences         |          |                                           |                                           |
| Vitamin D Analyte   | Same     | 25(OH) Vitamin D2                        | 25(OH) Vitamin D3                        |
| Forms               |          | 25(OH) Vitamin D3                        |                                           |
| Other Analytes      | None     | Contains also:                           |                                           |
|                     |          | Anti-Tg                                  |                                           |
|                     |          | Anti-TPO                                 |                                           |
|                     |          | C-peptide                                |                                           |
|                     |          | Erythropoietin (EPO)                     |                                           |
|                     |          | Intact PTH (iPTH)                        |                                           |
|                     |          | IGF-I                                    |                                           |
|                     |          | Osteocalcin                              |                                           |
| Storage (unopened)  | 12 months at 2 to 8°C                    | 2 years at -20°C to -70°C                |
| Form                | Lyophilized                              | Liquid                                   |

K. Standard/Guidance Document Referenced (if applicable):

EN standard, 13640 – Stability testing of In Vitro diagnostic reagents.

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

      Not applicable

   b. Linearity/assay reportable range:

      Not applicable

   c. Traceability, Stability, Expected values (controls, calibrators, or methods):

      Traceability
      The Vitamin D2 and D3 antigen material were obtained from commercial vendors. The
Vitamin D2 and D3 antigen material are supplied as a white solid. The Vitamin D2 and Vitamin D3 antigens are solubilized in 95% Ethyl Alcohol and subsequently spiked into the 25-hydroxy Vitamin D2/D3 Control Matrix to manufacture the Vitamin D Level 1, 2, and 3 controls.

**Value Assignment:**
- The control ranges as determined using DiaSorin LIAISON, DiaSorin RIA, IDS EIA and LC-MS/MS assays are provided in the assigned value sheet for each lot release. Each control range was determined from a minimum of 20 measurements per assay using 2 reagent/calibrator lots, 2 instruments, in 2 runs with 5 replicates each run. The ranges were determined as mean +/- 2 SD for DiaSorin LIAISON, DiaSorin RIA assays or mean +/-30% for IDS EIA and LC-MS/MS assays.
- In the labeling the sponsor recommends that each end user laboratory establish its own means and acceptable ranges and use the assigned value sheet as guidance only.

**Stability:**
- Shelf life stability:
  Real-time testing at 2-8°C were conducted and is still on-going. The stability study protocol and acceptance criteria have been reviewed and found to be acceptable. The current test results support a shelf life of 12 months at 2-8°C.
- Reconstituted Stability:
  The stability study protocol and acceptance criteria to determine the reconstituted stability and freeze/thaw cycle of the controls have been reviewed and found to be acceptable. The control solutions are stable for 14 days when stored tightly capped at 2-8°C, and stable for 63 days when stored at -10°C. Controls may be frozen and thawed repeatedly for up to 9 cycles

**d. Detection limit:**
Not applicable

**e. Analytical specificity:**
Not applicable

**f. Assay cut-off:**
Not applicable

2. **Comparison studies:**

   **a. Method comparison with predicate device:**
Not applicable

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The control ranges as determined using DiaSorin LIAISON, DiaSorin RIA, IDS EIA and LC-MS/MS assays are provided in the assigned value sheet for each lot release.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.