

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k123983

B. Purpose for Submission:

New assay

C. Measurand:

25-hydroxyvitamin D and other hydroxylated metabolites

D. Type of Test:

Quantitative, chemiluminescent immunoassay

E. Applicant:

Qualigen, Inc.

F. Proprietary and Established Names:

FastPack® Vitamin D Immunoassay

FastPack® Vitamin D Calibrator Kit

FastPack® Vitamin D Control Kit

FastPack® Vitamin D Method Verification Kit

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1825, Vitamin D Test System; 21 CFR 862.1150, Calibrator; 21 CFR 862.1660, Quality Control Material (Assayed and Unassayed)

2. Classification:

Class II for test and calibrator; class I, reserved for control

3. Product code:

MRG, JIT, JJX

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use.

2. Indication(s) for use:

FastPack® Vitamin D Immunoassay is intended for the quantitative determination of total 25-hydroxyvitamin D and other hydroxylated metabolites in human serum and plasma. The assay is to be used as an aid in the assessment of vitamin D sufficiency in adults. The FastPack® Vitamin D Immunoassay is intended for use with the FastPack® Analyzer.

FastPack® Vitamin D Calibrator Kit is used for calibrating the quantitative FastPack® Vitamin D Immunoassay on the FastPack® Analyzer.

FastPack® Vitamin D Control Kit is used for quality control of the FastPack® Vitamin D Immunoassay on the FastPack® Analyzer.

FastPack® Vitamin D Method Verification Kit is used in the quantitative verification of calibration and assay range of the quantitative FastPack® Vitamin D Immunoassay on the FastPack® Analyzer.

3. Special conditions for use statement(s):

For prescription use only.

4. Special instrument requirements:

FastPack® Analyzer

I. Device Description:

The devices cleared under this 510(k) are:

- a) FastPack® Vitamin D Immunoassay
- b) FastPack® Vitamin D Calibrator Kit
- c) FastPack® Vitamin D Control Kit
- d) FastPack® Vitamin D Method Verification Kit

The FastPack® Vitamin D Immunoassay kit contains 50 FastPack® Vitamin D Reagent Packs and 52 FastPack® Vitamin D Pretreatment Vials. Each FastPack® Vitamin D Reagent Pack contains a vitamin D antibody solution (containing a mouse monoclonal anti 25-OH vitamin D antibody conjugated to alkaline phosphatase in a protein matrix containing a preservative), paramagnetic particles (containing Biotin-25-OH vitamin D bound to streptavidin-coated paramagnetic particles in buffer containing 0.1% Proclin300 as a preservative), substrate solution (Immunoglow Plus™ containing indoxyl-3-phosphate and lucigenin in buffer containing preservatives) and wash buffer (Tris buffer containing surfactants). Each FastPack® Vitamin D Pretreatment Vial contains sample pretreatment solution (Perfluorooctanoic acid in purified water and 0.1% Proclin 300 as a preservative). All calibrators, controls, and serum samples need to be pre-treated by diluting 1:3

with vitamin D pretreatment buffer (1 part sample, 2 parts pretreatment buffer).

The FastPack® Vitamin D Calibrator kit contains one level calibrator containing delipidated vitamin D-free human serum, protein stabilizers in Tris buffer 0.1% sodium azide and 0.05% Proclin 950. It is a zero calibrator i.e. there is no vitamin D analyte in the calibrator.

The FastPack® Vitamin D Control kit contains two level control solutions (control 1, 14.0 to 40.0 ng/mL; control 2, 39.0 to 91.0 ng/mL). The control solutions contain components of human origin prepared in a Tris buffer with protein stabilizers, 0.1% sodium azide and 0.05% Proclin 950.

The FastPack® Vitamin D Method Verification kit contains three level verifier solutions. The verifier solutions (low- <12.9 ng/mL, mid- 65 to 85 ng/mL and high- ≥150 ng/mL verifiers) contain components of human origin prepared in a Tris buffer with protein stabilizers, 0.1% sodium azide and 0.05% Proclin 950.

Human source materials are screened for HIV, HBV and HCV using FDA approved tests and only materials negative for the above viruses are used in the manufacturing of the kit reagents.

J. Substantial Equivalence Information:

1. Predicate device name(s):

DiaSorin LIAISON® 25-Hydroxy Vitamin D TOTAL Assay

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

k112725

3. Comparison with predicate:

| Item | Candidate Device: Qualigen FastPack® Vitamin D Immunoassay (k123983) | Predicate Device: DiaSorin LIAISON® 25-Hydroxy Vitamin D TOTAL Assay (k112725) |
|---------------------------------------|--|---|
| Intended Use / Indications for Use | For the in-vitro quantitative determination of total 25-hydroxyvitamin D and other hydroxylated metabolites in human serum and plasma. The assay is to be used as an aid in the assessment of vitamin D sufficiency in adults. | Same. |
| Sample Type | Serum or plasma (EDTA or lithium heparin) | Serum only |
| Sample Preparation | Standard processing for serum and plasma | Standard processing for serum |
| Interpretation of Results | Standard Curve | Same |

| Item | Candidate Device: Qualigen FastPack® Vitamin D Immunoassay (k123983) | Predicate Device: DiaSorin LIAISON® 25-Hydroxy Vitamin D TOTAL Assay (k112725) |
|--------------------------|---|---|
| Methodology | A paramagnetic particle based direct competitive chemiluminescence immunoassay | Same |
| Testing Environment | Prescription use only | Same |
| Platform | FastPack® Analyzer | LIAISON® Analyzer family |
| Assay Principle | Chemiluminescence | Same |
| Assay Procedure | Automated | Same |
| Assay Time (approximate) | Ten minutes | Twenty minutes |
| Assay Range | 12.9. to 150 ng/mL | 4.0 to 150 ng/mL |
| Traceability | Internal standards (9 levels) assigned based on patient correlation with LIAISON® 25-OH Vitamin D TOTAL assay | Standardized using UV quantification of 25-OH Vitamin D |
| Precision | Within-run: ≤ 15.1% Between-run: ≤ 4.9% Total: ≤ 15.1% | Within-run: ≤ 7.7% Between-run: ≤ 3.2% Total: ≤ 12.6% |
| Linearity | Assay linear from LoQ (12.9 ng/mL) to 150 ng/mL | Assay linear from LoQ (4.0 ng/mL) to 150 ng/mL |
| Interfering Substances | No interference observed at the listed concentrations: bilirubin – 40 mg/dL Biotin – 1000 ng/mL Hemoglobin – 500 mg/dL cholesterol – 500 mg/dL Lipids – 250 mg/dL total protein – 10.7 g/dL | No interference from high levels of bilirubin, hemoglobin, triglycerides, uric acid, IgG, albumin and cholesterol. |
| Cross Reactivity | ≥100% cross-reactivity with 25-OH D2, 25-OH D3, and 24,25-(OH)2-Vitamin D3; <10% cross-reactivity with Vitamin D2, Vitamin D3, 1,25-(OH)2-Vitamin D2, 1,25-(OH)2-Vitamin D3, 3-epi-25(OH) Vitamin D3, 24,25-(OH)2-Vitamin D2, and Paricalcitol | ~100% cross-reactivity with 25 OH D2, 25 OH D3; <10% cross-reactivity with Vitamin D2, Vitamin D3, 3-epi-25OH Vitamin D3, 1,25-(OH)2-Vitamin D2, and 1,25-(OH)2-Vitamin D3 |

| Item | Candidate Device: Qualigen FastPack® Vitamin D Calibrators (k123983) | Predicate Device: DiaSorin LIAISON® 25-Hydroxy Vitamin D TOTAL Assay (k112725) |
|--------------|---|---|
| Intended Use | For <i>in vitro</i> diagnostic use in calibrating Vitamin D Assay | Same |

| Item | Candidate Device: Qualigen FastPack® Vitamin D Calibrators (k123983) | Predicate Device: DiaSorin LIAISON® 25-Hydroxy Vitamin D TOTAL Assay (k112725) |
|-----------------------------|---|---|
| Antigen Used in Calibrators | No antigen present | Antigen present |
| Storage Temperature | 2 to 8°C | Same |
| Number of Calibrators | One | Two |
| Matrix | Human serum-based matrix containing preservative and stabilizers | Human serum-based matrix containing preservative |
| Open vial stability | 60 days | 4 weeks |

| Item | Candidate Device: Qualigen FastPack® Vitamin D Controls (k123983) | Predicate Device: DiaSorin LIAISON® 25-Hydroxy Vitamin D TOTAL Assay Assay (k112725) |
|--------------------------|---|---|
| Intended Use | For <i>in vitro</i> diagnostic use to monitor the precision and accuracy of the Vitamin D Assay | Same |
| Antigen Used in Controls | 25-(OH) Vitamin D | Same |
| Storage Temperature | 2 to 8°C | Same |
| Number of levels | 2 | Same |
| Matrix | Human serum-based matrix containing preservative and stabilizers | Human serum-based matrix containing preservative |
| Open vial stability | 30 days | No open vial stability claimed |

| Item | Candidate Device: Qualigen FastPack® Vitamin D Verifiers (k123983) | Predicate Device: DiaSorin LIAISON® 25-Hydroxy Vitamin D TOTAL Assay Assay (k112725) |
|--------------------------|---|---|
| Intended Use | For use in the quantitative verification of calibration and assay range of the Vitamin D Immunoassay. | Same |
| Antigen Used in Controls | 25-(OH) Vitamin D | Same |
| Storage Temperature | 2 to 8°C | Same |
| Number of levels | Three (low, mid and high levels) | Four |
| Matrix | Human serum-based matrix containing preservative and stabilizers | Human serum-based matrix containing preservative |
| Open vial stability | Single Use – Not applicable. | 4 weeks |

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

EP5-A2: Evaluation of Precision Performance of Quantitative Measurement Methods

EP6-A: Evaluation of the Linearity of Quantitative Measurement Procedures

EP7-A2: Interference Testing in Clinical Chemistry

EP9-A2IR: Method Comparison and Bias Estimation Using Patient Samples

EP17-A: Protocols for Determination of Limits of Detection and Limits of Quantitation

I/LA30-A: Immunoassay Interference by Endogenous Antibodies

L. Test Principle:

The FastPack® Vitamin D Immunoassay is a paramagnetic particle chemiluminescence immunoassay based on the “competitive” principle. The endogenous vitamin D in the sample is mixed with the pretreatment buffer, and added to the pack. The mixture is then incubated with a monoclonal anti-vitamin D antibody labeled with the alkaline phosphatase. The vitamin D in the pre-treated patient sample (or control or calibrator) reacts with the antibody. This immunoreactant complex is then incubated with the second reagent containing vitamin D covalently coupled to biotin that is pre-bound to streptavidin-coated paramagnetic particles. The antibody-alkaline phosphatase conjugate not reacted with the sample will bind to the unoccupied binding sites of the vitamin D-biotin-streptavidin coated paramagnetic particles. After the second incubation, the paramagnetic particles are repeatedly washed with wash buffer to remove unbound materials. The bound labeled-antibody to the paramagnetic beads is detected by adding the chemiluminogenic substrate. The resulting “glow” chemiluminescence is measured on the FastPack® Analyzer. The amount of bound labeled-antibody is inversely proportional to the concentration of vitamin D in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility Study:

Precision of the FastPack Vitamin D immunoassay was evaluated according to CLSI EP5-A2 guideline. Four spiked serum samples (approximately 25, 30, 45 and 80 ng/mL) were tested in duplicate determinations in each of two runs per day on each of two FastPack analyzers, each paired with an individual reagent lot over a period of 20 days to yield 160 replicates of each sample (N=80 on each analyzer/reagent pair). The results are tabulated below:

| Instrument / Reagent lot | Serum Sample (ng/mL) | Within-Run | | Between-Run | | Between-Day | | Total | |
|--------------------------|----------------------|------------|------|-------------|-----|-------------|-----|-------|------|
| | | Mean | SD | %CV | SD | %CV | SD | %CV | SD |
| Analyzer1 / Reagent Lot1 | 27.3 | 2.8 | 10.2 | 1.3 | 4.9 | 1.9 | 7.1 | 3.7 | 13.4 |
| | 31.1 | 3.3 | 10.7 | 0.0 | 0.0 | 1.8 | 5.7 | 3.8 | 12.1 |
| | 45.5 | 3.9 | 8.5 | 0.0 | 0.0 | 2.0 | 4.3 | 4.3 | 9.5 |
| | 84.9 | 4.1 | 4.8 | 0.0 | 0.0 | 3.2 | 3.7 | 5.1 | 6.1 |
| Analyzer2 / Reagent Lot2 | 25.9 | 3.9 | 15.1 | 0.0 | 0.0 | 0.0 | 0.0 | 3.9 | 15.1 |
| | 32.7 | 3.7 | 11.2 | 0.0 | 0.0 | 2.0 | 6.0 | 4.2 | 12.7 |
| | 46.1 | 3.5 | 7.5 | 0.0 | 0.0 | 1.2 | 2.6 | 3.7 | 7.9 |
| | 76.4 | 3.2 | 4.1 | 0.0 | 0.0 | 1.7 | 2.3 | 3.6 | 4.7 |

b. *Linearity/assay reportable range Study:*

Linearity of the FastPack Vitamin D assay was evaluated according to CLSI EP6-A. A high serum sample pool with pre-assigned value of 165.2 ng/mL was tested neat and mixed in various dilution ratios with a low serum sample pool with an estimated value of 10.0 ng/mL (below LoQ) to make a total of nine samples for testing the linearity of the assay. All samples were run in duplicate on one FastPack instrument using one lot of FastPack reagents and one FastPack calibrator lot. The linear regression equation yielded a slope of 0.9798, intercept of 4.5 and regression coefficient R² of 0.9973 for the measured sample range from 11.3 to 165.2 ng/mL. The result of the study supports the sponsor's claim that the assay is linear across the measuring range of 12.9 to 150 ng/mL.

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

Traceability:

The in-house reference standards are traceable to the predicate method (DiaSorin LIAISON® 25-Hydroxy Vitamin D TOTAL Assay).

Preparation of in-house reference standard solutions:

In-house reference standards are prepared from delipidated human serum which is spiked with an ethanolic solution of commercially available vitamin D₃ (certified to be ≥98% pure as verified by HPLC), in order to produce nine concentration levels ranging from 0 to 190ng/mL.

Value Assignment:

A method comparison was performed using 86 patient samples between FastPack and DiaSorin LIAISON® 25-Hydroxy Vitamin D TOTAL Assay (Predicate Device). The resulting FastPack RLUs were fitted to DiaSorin LIAISON concentration values using 4 parameter logistic curve fit. This curve was then used to value assign the in-house reference standards which

were tested using multiple lots of FastPack Vitamin D reagent on multiple FastPack Analyzers.

Master Curve Generation:

During the FastPack reagent pack production process, Qualigen generates a master standard curve and places this information in the barcode of each FastPack label, where it can be read by the FastPack Analyzer during the testing sequence. The assay master curve is generated by testing 9 levels of reference standards. Each level is tested in multiple replicates on multiple FastPack Analyzers. The resulting values are normalized against a reference calibrator target value. The mean of the normalized RLUs from multiple analyzers is then curve fit against the standard concentrations using standard curve fitting math model.

FastPack® Vitamin D Calibrator Kit:

The value assignments of the in-house reference calibrators are based on an internal procedure using an in-house reference standard (traceable to HPLC for purity assessment) to make 9 concentrations. The factory calibration information is provided in the calibration card that is provided with the calibrator kit. Only one level of calibrator (zero level) is provided in the calibrator kit, and the user must calibrate the assay with this calibrator once every 21 days or whenever a new lot of FastPack Vitamin D immunoassay reagent packs are to be used.

FastPack® Vitamin D Control Kit and Method Verification Kit:

Controls and verifiers are value assigned using an internal procedure with multiple replicates run on multiple instruments using multiple lots of reagent. The average concentration values of the results are used to establish the control target value. The expected range for the two controls is: Control 1, 14 to 40 ng/mL; Control 2, 39 to 91 ng/mL. The Verifier assigned values are: Low verifier, <12.9 ng/mL; Mid verifier, target range is 75±10 ng/mL; High verifier, ≥150 ng/mL.

Stability:

Shelf-life and open-vial stability for the calibrator, controls and verifiers are based on real-time stability study and is still on-going. Shelf-life claim for the calibrator, controls and verifiers is 90 days when stored at 2-8°C. Open-vial stability for the calibrator is 60 days and control is 30 days when stored at 2-8°C. There is no open-vial claim for the verifiers since they are intended for single use. Stability study protocols and acceptance criteria has been reviewed and found to be adequate.

d. Detection limit Study:

The LoB, LoD, and LoQ were determined according to protocols in CLSI EP-17A.

LoB was determined based on 160 replicates of a blank sample (10 replicates

on each of eight different FastPack analyzers using 2 lots of FastPack reagents and a single FastPack Calibrator lot). Blank sample used was a delipidated Vit D-free human serum. LoB is determined to be 2.3 ng/mL.

LoD was determined to be 6.2 ng/mL.

LoD and LoQ was determined using four low-level samples formulated by mixture of a patient sample pool with the blank sample (delipidated Vitamin D-free human serum) to yield target concentrations of 2.1, 5.6, 11.8 and 15.4 ng/mL of Vitamin D. Each sample were tested in replicates of ten on three FastPack analyzers using two lots of FastPack reagents and a single FastPack calibrator lot (N=60 per sample). The %CV was calculated for all four low samples tested. From the plot of the observed Vitamin D concentrations versus the %CV obtained, the LoQ is estimated to be 12.9 ng/mL with 20%CV.

The sponsor claims that the 25-OH Vitamin D assay has a measuring range of 12.9 to 150 ng/mL.

e. *Analytical specificity:*

Cross-reactivity Study:

Serum sample pools at ~30 and ~60 ng/mL were tested without and with two levels of various potentially cross-reacting compounds. Each sample was tested in triplicate on one FastPack instrument with one lot of FastPack reagents and one FastPack calibrator lot. The results are presented in the table below:

| Cross-reactant | Maximum Concentration tested (ng/mL) | Percent Cross-reactivity (%) |
|-----------------------------|---|-------------------------------------|
| 1,25-dihydroxy Vitamin D2 | 100 | 4.0 |
| 1,25-dihydroxy Vitamin D3 | 100 | 9.8 |
| Vitamin D2 | 500 | 2.0 |
| Vitamin D3 | 500 | 1.9 |
| 25-hydroxy Vitamin D3 | 25 | 106.0 |
| 25-hydroxy Vitamin D2 | 100 | 93.0 |
| 24,25-dihydroxy Vitamin D3 | 20 | 117.4 |
| 24,25-dihydroxy Vitamin D2 | 40 | -0.9 |
| 3-epi-25-hydroxy Vitamin D3 | 400 | 7.8 |
| Paricalcitol | 200 | -1.2 |

Interference Study:

Bilirubin, biotin, cholesterol, total protein, lipids and hemoglobin were tested at concentrations up to 40 mg/dL, 1000 ng/mL, 1000 mg/dL, 13.2 g/dL, 400 mg/dL and 500 mg.dL, respectively by spiking these final concentrations in to two serum pools, a low (~30 ng/mL Vitamin D) and a high (~60 ng/mL Vitamin D). Each sample was tested in triplicate with one lot of FastPack reagent and one lot of calibrator on one FastPack analyzer. No significant interference was defined as % recovery of $\pm 10\%$. The results are as shown below:

| Interferent | No interference up to |
|-----------------------|-----------------------|
| Bilirubin | 40.0 mg/dL |
| Biotin | 1000 ng/mL |
| Cholesterol | 500 mg/dL |
| Total Protein | 10.7 g/dL |
| Hemoglobin | 500 mg/dL |
| Lipids (Triglyceride) | 250 mg/dL |

Since lipemic sample affect the vitamin D level, the sponsor has the following limitation in the labeling:

Under ‘Specimen Collection/Preparation’, “Samples showing turbidity (high lipid content) should not be used.”

Under ‘Limitations’, “Do not use lipemic sample because lipemic sample will generate falsely low result”

HAMA and Rheumatoid factor Interference:

A low and a high serum pool at Vitamin D concentrations of ~30 and 90 ng/ml. Aliquots of each were spiked with a commercial RF control serum or commercial HAMA preparation at various concentrations. Unspiked and spiked aliquots were run in triplicate on one FastPack analyzer using one FastPack reagent lot and one FastPack calibrator lot. Percent differences between the spiked and unspiked samples are $\leq 10\%$. The results are shown below:

| Interferent | No interference up to |
|-------------------|-----------------------|
| Rheumatoid Factor | 600 IU/mL |
| HAMA | 4000 ng/mL |

The sponsor has the following limitations in the labeling:

“Specimen from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-

mouse antibodies (HAMA). Such specimens may show either falsely elevated or depressed values when tested with assay kits employing mouse monoclonal antibodies.”

“Heterophilic antibodies in a sample have the potential to cause interference in immunoassay systems. Infrequently, vitamin D levels may appear depressed or elevated due to heterophilic antibodies present in the patient’s sample or to nonspecific protein binding. If the vitamin D level is inconsistent with clinical evidence, additional vitamin D testing is suggested to confirm the result.”

f. Assay cut-off:

Not applicable – this is a quantitative assay.

2. Comparison studies:

a. *Method comparison with predicate device:*

Method comparison study was conducted to evaluate the performance of FastPack Vitamin D immunoassay compared to the predicate device, DiaSorin LIAISON® 25-Hydroxy Vitamin D TOTAL Assay. Serum samples (all natural) from 137 subjects tested singlet were used in the study. Deming regression was performed. The results are presented below:

| Parameter | Results |
|----------------------|----------------------|
| Slope (95% CI) | 0.97 (0.88 to 1.06) |
| y-intercept (95% CI) | -4.6 (-8.9 to -0.25) |
| R (95% CI) | 0.92 (0.90 to 0.94) |
| Sample range tested | 18.6 to 132.6 ng/mL |

b. *Matrix comparison:*

Blood samples from 32 volunteers were processed in parallel to collect serum, lithium-heparin plasma and EDTA plasma. The samples were tested in duplicate on two FastPack analyzers using one lot of reagents, calibrator and controls using the FastPack Vitamin D immunoassay. Deming regression was performed to compare a) serum and EDTA plasma, and b) serum and lithium-heparin plasma values. The Deming regression results are presented below:

| Parameter | Serum vs Lithium-heparin plasma | Serum vs EDTA plasma |
|-----------------------------|---|--|
| Number of samples | 32 | 32 |
| Concentration range (ng/mL) | Serum: 17.4 to 139.5 Lithium-heparin plasma: 20.9 to 133.3 | Serum: 17.4 to 139.5 EDTA plasma: 14.9 to 134.1 |
| Slope | 0.970 | 0.993 |
| y-intercept | -0.703 | -6.294 |
| Corr. coefficient (R) | 0.971 | 0.979 |
| R ² | 0.943 | 0.959 |

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; this is a quantitative assay.

5. Expected values/Reference range:

A reference range study was performed using serum samples from 367 subjects. The samples were acquired from four different sources representing five different geographic regions of US. Sampling took place during four months that covered late Winter to early Summer, representing a range of exposure to sunlight and weather conditions. The inclusion criteria were age (21 to 90 years) and good health. The exclusion criteria included Vitamin D supplementation of ≥ 2000 IU/day, family history of parathyroid disease, thyroid disease or calcium regulatory disease, current/previous history of kidney, GI, liver, calcium-level, thyroid, or parathyroid disease, current/previous history of seizures, chronic disease, or bariatric surgery, and current medications including cholesterol absorption inhibitors, anticonvulsants, glucocorticoids, and anti-rejection medications. Subjects ranged in age from 21 to 88 years, skin pigmentations from dark to medium to light, and gender (Female, 40.3% and Male, 59.7%). Based on the study, the central 95th range of the expected Vitamin D values for adults is 13.7 to 57.3 ng/mL.

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.