510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

k141914

B. Purpose for Submission:

New Device

C. Measurand:

Capillary whole blood glucose from finger, palm, forearm, upper arm, calf or thigh.

D. Type of Test:

Quantitative amperometric assay (Glucose oxidase)

E. Applicant:

OK BIOTECH CO. LTD.

F. Proprietary and Established Names:

Prodigy AutoCode Eject™ Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1345, Glucose test system

2. Classification:
   Class II

3. Product code:
   NBW, System, Test, Blood Glucose, Over the Counter
   CGA, Glucose Oxidase, Glucose

4. Panel:
   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   Prodigy® AutoCode® Eject Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh. The Prodigy® AutoCode® Eject Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The Prodigy® AutoCode® Eject Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Prodigy® AutoCode® Eject Blood Glucose Monitoring System should not be used for the diagnosis of, or screening for diabetes, or for neonatal use. The alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

   PRODIGY® No Coding Test Strips are intended for use with the PRODIGY® AutoCode® Eject blood glucose meter to measure the concentration of the blood glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh for self-testing at home. They are for testing outside the body (in vitro diagnostic use only). Do not use them for diagnosis of, or screening for diabetes or for testing on neonates. PRODIGY® No Coding Test Strips are used as an aid to monitor the effectiveness of diabetes control.

   This system contains a speaking function, but is not intended for use by the visually impaired.

3. Special conditions for use:
   - For over-the-counter use
   - Not for neonatal use
   - Not for screening or diagnosis of diabetes mellitus
   - Not for use on critically ill patients, patients in shock, dehydrated patients or hyper-osmolar patients
   - For single-patient use only
   - Alternative site testing (AST) testing should only be done during steady-state times (when glucose is not changing rapidly, for example after meals, exercise, or after taking insulin.).
   - AST should not be used to calibrate continuous glucose monitors (CGMs).
   - AST should not be used for insulin dose calculations.

4. Special instrument requirements:

   Prodigy AutoCode Eject™ Blood Glucose Meter

I. Device Description:

The Prodigy Auto Code Eject™ Blood Glucose Monitoring System consists of the Prodigy Auto Code Eject Blood Glucose Meter, Prodigy No Coding Test Strips and two levels of Prodigy Control Solutions (Level 1 and Level 2). The System also comprises batteries, a carrying case, lancets, and User Manual. The Prodigy Auto Code Eject Blood Glucose Meter includes a voice function, and the ability to store and average blood test results.

Each test strip contains the following reagent composition: Glucose oxidase (Aspergillus Niger) 0.4%, Potassium ferricyanide 3.8% and other non-reactive ingredients. The Prodigy No Coding Test Strips are available for purchase separately.

Each vial of control solutions contains 4.0mL of Level or Level 2 Prodigy Control Solution. These control solutions are available for purchase separately.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   PRODIGY Preferred® Blood Glucose Monitoring System

2. Predicate K number(s):

   k122338

2. Comparison with predicate:

Similarities/Differences		
Item	Predicate Device k122338 PRODIGY Preferred® Blood Glucose Monitoring System	Candidate Device k141914 Prodigy Auto-Code Eject Blood Glucose Monitoring System
Indications for Use	It is intended for quantitative measurement of glucose in fresh capillary blood by people with diabetes at home as an aid to monitor the effectiveness of diabetes control.	Same
Test strip used	Prodigy No Coding Test Strips	Same
Control solutions used	Prodigy Control Solution Level 1/Level 2	Same
Detection method	amperometric	Same
Enzyme	Glucose oxidase	Same
Specimen type	Capillary whole blood from fingertip and palm, forearm, upper-arm, calf and thigh	Same
Operating conditions	50ºF to 104ºF (10ºC to 40ºC), 10-85% R.H.	Same

HCT range	20-60%	Same
Detection range	20-600 mg/dL	Same
Measuring time	7 seconds	6 seconds
Meter size	71 mm (L) × 60 mm (W) × 19 mm (H)	100 mm (L) × 56 mm (W) × 23 mm (H)
Meter weight	45 g with battery	79 g with battery
Power battery	3V CR2032 battery	1.5 V AAA Alkaline batteries
Memory storage	120 tests	450 tests
Speaking function	No	Yes

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

1. CLSI - EP6-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline
2. IEC – 60601 – 1- 2; 2001, Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility-Requirements and Tests
3. IEC – 61010 – 1; 2010, Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements
4. IEC/EN – 61010-2-101; 2009, Safety requirements for electrical equipment for measurement, control and laboratory use- Part2 – 101: Particular requirements for in vitro diagnostic (IVD) medical equipment

L. Test Principle:

The test is based on the measurement of electrical current generated by the reaction of capillary whole blood glucose with glucose oxidase on the test strip. The meter measures the strength of the current which is proportional to the concentration of glucose present and displays the corresponding blood glucose level.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   The sponsor performed within-run precision studies using venous whole blood samples spiked to five different glucose concentration levels (30 to 50, 51 to 110, 111 to 150, 151 to 250, 251 to 400 mg/dL). Each glucose concentration level was analyzed in replicates of 10, with 3 test strip lots, and 10 meters, for a total of 300 tests per each glucose level for each meter. Results are summarized below:

Lot 1				
Glucose Level (mg/dL)	Mean (mg/dL)	n	SD (mg/dL)	%CV
30 to 50	43.1	100	2.4	5.1
51 to 110	78.6	100	2.7	3.4
111 to 150	129.4	100	3.7	2.8
151 to 250	195.4	100	4.8	2.4
251 to 400	327.2	100	8.9	2.7

Lot 2				
Glucose Level (mg/dL)	Mean (mg/dL)	n	SD (mg/dL)	%CV
30 to 50	43.2	100	2.4	5.6
51 to 110	79.0	100	2.7	3.4
111 to 150	129.5	100	3.4	2.6
151 to 250	194.9	100	5.0	2.6
251 to 400	327.1	100	8.8	2.7

Lot 3				
Glucose Level (mg/dL)	Mean (mg/dL)	n	SD (mg/dL)	%CV
30 to 50	43.6	100	2.2	5.0
51 to 110	79.0	100	2.5	3.2
111 to 150	129.7	100	3.5	2.7
151 to 250	194.7	100	5.4	2.8
251 to 400	328.9	100	8.8	2.7

Intermediate (between run) Precision was evaluated using 3 levels of glucose control solutions (30 – 50 mg/dL; 96 – 144 mg/dL and 200 – 300 mg/dL) over 10 days with 3 test strip lots. For each level, on each day, 5 meters were used for testing, with 10 replicates collected per meter for a total of 50 replicates per day for each glucose level.

Precision pooled over 10 days:

Lot 1				
Glucose Level (mg/dL)	Mean (mg/dL)	n	SD (mg/dL)	%CV
30 - 50	49.9	50	2.6	
96 - 144	118.3	50	3.7	3.1%
200 - 300	249.8	50	8.0	3.2%

Lot 2				
Glucose Level (mg/dL)	Mean (mg/dL)	n	SD (mg/dL)	%CV
30 - 50	50.1	50	2.0	
96 - 144	117.6	50	3.6	3.1%
200 - 300	254.1	50	9.0	3.5%

Lot 3				
Glucose Level (mg/dL)	Mean (mg/dL)	n	SD (mg/dL)	%CV
30 - 50	49.9	50	2.0	
96 - 144	118.9	50	3.8	3.2%
200 - 300	253.2	50	8.8	3.5%

b. Linearity/assay reportable range:

Linearity testing was performed using venous whole blood samples. The evaluation was conducted with 10 meters and 3 test strip lots. Samples with the following glucose concentrations (mg/dL) were prepared: 20, 50, 90, 150, 250, 300, 350, 400, 450, 510, and 600.

Low samples were prepared by allowing glycolysis to occur. High samples were prepared by spiking into the venous whole blood samples. Values were confirmed using a laboratory reference method (YSI 2300 analyzer) calibrated with NIST reference material.

Ten strips from each lot were used for testing at each glucose concentration for a total of n=30 tests per glucose concentration. The evaluation yielded the following regression equation based on all samples:

Lot	Slope	y-intercept	R^2
1	0.9927	4.6355	0.9978
2	0.9952	3.6973	0.9973
3	0.9964	2.2992	0.9982

The results of the study support the sponsor's claimed glucose measuring range of 20-600 mg/dL.

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

Traceability:
The system is traceable to the NIST SRM #917c glucose reference material.

Test strips and control solutions were previously cleared in k122338.

Control Solution Value Assignment and Stability:
Value Assignment protocols and acceptance criteria for the 2 levels of control solutions were evaluated and found to be acceptable in k122338. The ranges for each control solution are provided on the test strip vial label. Stability protocols and acceptance criteria for the control solutions were evaluated in k122338 and found to be acceptable to support closed-vial stability of 24 months at 39-86°F and open-vial stability of 90 days when stored at the recommended storage temperature (39-86°F) or until the expiration date printed on the label, whichever comes first.

Test Strip Stability:
Stability protocols and acceptance criteria for the Prodigy No Coding Test Strips were evaluated in k122338 and found to be acceptable to support closed-vial stability of 24 months at 39-104°F and open-vial stability of 90 days when test strips are stored at the recommended storage temperature (39-104°F) and 10-85% relative humidity or until the expiration date printed on the label, whichever comes first. The labeling instructs the users not to freeze the test strips.

d. Detection limit:

See linearity study in Section M1b above. The meter displays "Lo" with glucose values below 20mg/dL, and "HI" with glucose values over 600 mg/dL.

e. Analytical specificity:

Interference studies were performed by spiking endogenous and exogenous substances into venous whole blood. Each potential interferent was tested at three glucose levels (approximately 80, 250, and 450 mg/dL). Ten replicates were measured for each test sample. Results of test samples measured on the Prodigy Auto-Code Eject Blood Glucose Meter System were compared to samples measured on a laboratory-based reference method (YSI 2300 analyzer) and bias and percent bias were calculated. This procedure was performed for 3 test strip lots. The compounds at the concentrations listed below did not affect results (defined by the sponsor as percent bias $\leq$ 10%):

Interfering substance	Concentration with no Significant Interference
Acetaminophen	8.0 mg/dL
Ascorbic acid	5.0 mg/dL
Aspirin	60 mg/dL
Bilirubin	90 mg/dL
Cholesterol	500 mg/dL
Creatinine	5.0 mg/dL
Dopamine	2.0 mg/dL
Galactose	900 mg/dL
Gentisic acid	5.0 mg/dL
Glutathione	53 mg/dL
Hydroxyurea	3.0 mg/dL
L-dopa	10 mg/dL
Maltose	900 mg/dL
Methyldopa	3.0 mg/dL
Tolazamide	100 mg/dL
Tolbutamide	400 mg/dL
Triglyceride	2,000 mg/dL
Uric acid	8.0 mg/dL
Xylose	100 mg/dL

Based on these results, the sponsor states the following limitation in their labeling: "The system exhibits interference from Acetaminophen. Do not use during acetaminophen treatment."

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

To assess system accuracy, results from the Prodigy Auto-Code Eject Blood Glucose Monitoring System were compared to a reference method (YSI 2300 analyzer). Venous samples and capillary samples from fingerstick, forearm, palm, upper arm, calf and thigh were obtained by professional users from 100 participants with glucose concentrations ranging from 44-414 mg/dL. To obtain extreme blood glucose concentrations, seven samples were altered. Results of linear regression of the first test from each participant are shown below:

Linear regression analysis:
Fingertip: y = 1.0137x - 2.9146 R^2 = 0.9883
Palm: y = 1.01x - 0.7405 R^2 = 0.9883
Forearm: y = 0.9963x + 0.4211 R^2 = 0.9865
Upper arm: y = 1.0095x - 0.8054 R^2 = 0.987
Calf: y = 1.0076x - 1.5091 R^2 = 0.9882
Thigh: y = 1.0076x - 1.5091 R^2 = 0.9882

Results are shown in the tables below:

Fingertip

For glucose concentrations < 75 mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	
9/15 (60%)	13/15 (87%)	15/15 (100%)	
For glucose concentrations ≥75 mg/dL			
Within ± 5%	Within ± 10%	Within ± 15% ±	Within ± 20 %
54/92 (59%)	79/92 (86%)	90/92 (98%)	92/92 (100%)

Palm

For glucose concentrations < 75 mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	
10/15(67%)	14/15 (93%)	15/15 (100%)	
For glucose concentrations ≥75 mg/dL			
Within ± 5%	Within ± 10%	Within ± 15% ±	Within ± 20%
58/92 (63%)	73/92 (79%)	88/92 (96%)	92/92 (100%)

Forearm

For glucose concentrations < 75 mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	
9/15 (60%)	13/15 (87%)	15/15 (100%)	
For glucose concentrations ≥75 mg/dL			
Within ± 5%	Within ± 10%	Within ± 15% ±	Within ± 20 %
57/92 (62%)	80/92 (87%)	91/92 (99%)	92/92 (100%)

Upper arm

For glucose concentrations < 75 mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	
9/15 (60%)	13/15 (87%)	15/15 (100%)	
For glucose concentrations ≥75 mg/dL			
Within ± 5%	Within ± 10%	Within ± 15% ±	Within ± 20 %
54/92 (59%)	78/92 (85%)	89/92 (97%)	92/92 (100%)

Calf

For glucose concentrations < 75 mg/dL		
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
10/15 (67%)	13/15 (87%)	15/15 (100%)

For glucose concentrations ≥75 mg/dL			
Within ± 5%	Within ± 10%	Within ± 15% ±	Within ± 20 %
60/92 (65%)	83/92 (90%)	90/92 (98%)	92/92 (100%)

Thigh

For glucose concentrations < 75 mg/dL		
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
9/15 (60%)	13/15 (87%)	15/15 (100%)

For glucose concentrations ≥75 mg/dL			
Within ± 5%	Within ± 10%	Within ± 15% ±	Within 205 %
53/92 (58%)	80/92 (87%)	89/92 (97%)	92/92 (100%)

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):

User Performance study:

To assess the performance of the Prodigy Auto-Code Eject Blood Glucose Monitoring System in the hands of the intended users, the sponsor performed a study with 109 lay user participants who collected and tested samples from their own fingertip, palm, forearm, upper arm, calf and thigh. Results were analyzed by comparing blood glucose results obtained by the lay users with the Prodigy Auto-Code Eject Blood Glucose Monitoring System against results obtained using a laboratory reference method (YSI 2300 analyzer). The glucose concentrations in the samples ranged from approximately 55.6 to 330 mg/dL as measured by the laboratory reference method. Results are summarized in the tables below:

For glucose concentrations <75 mg/dL

Site	Within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
Finger	16/22 (73%)	22/22 (100%)	22/22 (100%)
Palm	14/22 (64%)	21/22 (100%)	22/22 (100%)

Forearm	15/22 (73%)	21/22 (95%)	22/22 (100%)
Upper arm	16/22 (73%)	21/22 (95%)	22/22 (100%)
Calf	19/22 (86%)	22/22 (100%)	22/22 (100%)
Thigh	14/22 (64%)	21/22 (95%)	22/22 (100%)

For glucose concentrations ≥ 75 mg/dL

Site	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
Finger	44/87 (51%)	71/87 (82%)	80/87 (92%)	87/87(100%)
Palm	46/87 (53%)	71/87 (82%)	84/87 (97%)	87/87 (100%)
Forearm	46/87 (73%)	72/87 (83%)	82/87 (94%)	87/87 (100%)
Upper arm	56/87 (64%)	79/87 (91%)	87/87 (95%)	87/87 (100%)
Calf	52/87 (60%)	70/87 (80%)	83/87 (95%)	87/87 (100%)
Thigh	44/87 (51%)	72/87 (83%)	84/87 (97%)	87/87(100%)

Linear Regression Analysis:

Sample Site	Slope	Intercept	R^2	N	Glucose Concentration range (new meter) (mg/dL)
Fingertip	0.9915	0.0657	0.9681	109	55-392
Palm	1.0004	-0.6104	0.972	109	50-357
Forearm	0.9994	-0.4764	0.9712	109	52-342
Upper arm	0.9884	1.8124	0.9887	109	52-321
Calf	1.0031	-2.3851	0.977	109	53-363
Thigh	1.0006	-0.0014	0.9762	109	50-364

4. Clinical cut-off**:**

   Not applicable

5. Expected values/Reference range:
   The sponsor provided the following information for expected glucose values for

persons without diabetes:

The normal adult fasting blood glucose range for a nondiabetic person is Less than 100 mg/dL (5.55 mmol/L) and less than 140 mg/dL (7.77 mmol/L) up to 2 hours after meals.

Source: American Diabetes Association (September 22, 2014. http://www.diabetes.org/diabetesbasics/diagnosis/)

N. Instrument Name:

Prodigy Auto-Code Eject Blood Glucose Monitoring System

O. System Descriptions:

1. Modes of Operation:
   Each test strip is single use and requires a sample volume of >0.7 μL.

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes __X_____ or No _____.

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes _____ or No __X____.

2. Software:
   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes__X____ or No _____.

3. Specimen Identification:
   There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:
   The system is intended to be used with capillary whole blood from the finger, palm, forearm, upper arm, calf and thigh. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:
   Calibration is automatic. There is no user input for coding.

6. Quality Control
   Two levels of aqueous glucose control solutions are available (sold separately) for use

with this system. Instructions on how to order the control solutions are included in the user manual. The meter has a function for the user to select that they wish to run a control solution to prevent control results from being stored in the internal memory as patient results. Recommendations on when to test the control materials are provided in the labeling. The control solution readings are not included in the average of the patient results when the measurements are performed in the "control solution mode". An acceptable range for each control level is printed on the test strip vial label. The user is cautioned not to use the meter if the control result falls outside these ranges.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

1. Hematocrit Study: To evaluate the effect of hematocrit on the Prodigy Auto-Code Eject Blood Glucose Monitoring System, venous blood samples were adjusted to hematocrit levels of 15 %, 20 %, 30 %, 40 %, 60 % and 65 %. Each hematocrit level was tested at 5 glucose concentration intervals (30-50, 51-110, 11-150, 151-250, 251-400 mg/dL) for a total of 30 samples. The evaluation included 10 meters, each tested with 2 lots of test strips, with 10 replicates per lot per Hct level per glucose level (for a total of 20 replicates for each sample). Results from the meter were compared to results obtained using a laboratory-based reference measurement (YSI 2300 analyzer). The evaluation of percent bias relative to values obtained on the YSI 2300 analyzer demonstrated acceptable performance across the hematocrit range of 20-60%.

2. Altitude study To evaluate the effect of altitude on the Prodigy Auto-Code Eject Blood Glucose Monitoring System, meters were tested at 6 altitudes above sea level (298 ft; 2 920 ft; 4,790 ft; 6,234 ft; 8,563ft and 11,161 ft). Five glucose levels (43, 82,134,203, and 321 mg/dL) were tested at each altitude. The evaluation included three meters and three strip lots. Each lot included 6 replicates for a total of 18 replicates per glucose level/altitude combination. Results were compared to results obtained using a laboratory-based reference measurement (YSI 2300 analyzer) and demonstrated that altitudes up to 11,000 feet above sea level have no significant effect on blood glucose measurements from the Prodigy Auto-Code Eject system .

3. Sample Volume: To demonstrate the minimum sample volume, venous whole blood samples with volumes ranging from 0.5 -1.5 µL were tested. Sample concentrations included five glucose levels (0, 76.6, 112, 175, and 340 mg/dL) tested at each volume. Testing included 10 strips from each of 3 lots for each glucose concentration/sample volume combination for a total of 30 replicates per volume/glucose level combination. Ten meters were used during testing. Values obtained were compared to values obtained using a laboratory-based reference method (YSI 2300 analyzer) Results support the a minimum sample volume of 0.7 µL.

4. Temperature and humidity studies: To evaluate system performance under the extremes of the recommended temperature and humidity conditions, sample testing was performed at temperatures of 50, 77, and 104 ^{0}F, and RH of 10 and 85%; each temperature was tested at both RH conditions. Venous whole blood at glucose concentrations 48, 149, and 315 mg/dL were tested. The evaluation included 10 Prodigy Auto-Code Eject Meters, and 3 strip lots with a total of 30 replicates per glucose level/environmental condition combination. The results obtained on the Prodigy Auto-Code Eject glucose meter were compared to those obtained on the YSI

2300, and support the operating conditions of temperatures from 10-40^{0}C and RH from 10-85% in any combination.

5. Infection Control and Robustness Studies: The device is intended for single-patient use only. Disinfection efficacy testing on the surface materials of the meter demonstrated complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, PDI SUPER SANI-CLOTH germicidal disposable wipes (EPA Registration # 9480-4). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 520 cleaning and disinfection cycles (a total of 1040 wipes) designed to simulate 5 years of device use with a maximum frequency of cleaning and disinfection 2x/week.

6. EMC testing was certified (Universal Testing Inc., Taiwan) and compliance certificates were provided.

7. Flesch-Kincaid readability assessment was conducted on all labeling and demonstrated that the User Manual was written at a grade level of 7.8 and the test strip insert was written at a grade level of 7.9.

8. Usability: Users completed questionnaires regarding ease of use (on a scale of 1(disagree) to 5 (fully agree) as well as specific questions to test understanding of information in the user manual. Greater than 90% of participants agreed that instructions were effective and helpful and results were easy to understand. Participants were also given questions to assess their understanding of the material in the manual. More than 95% of participants scored 85% or higher.

9. The meter manual states that customer service is available (24 hours, 7 days a week) by calling 1-800-243-2636.

Q. Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

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