510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K232732

B Applicant

Co-Innovation Biotech Co., Ltd.

C Proprietary and Established Names

Rapid Marijuana (THC) Test Strip 20, Rapid Marijuana (THC) Test Dipcard 20, Rapid Marijuana (THC) Test Strip 50, Rapid Marijuana (THC) Test Dipcard 50

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LDJ	Class II	21 CFR 862.3870 -	

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Measurand:

Marijuana

C Type of Test:

Competitive binding, lateral flow immunochromatographic assay.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

Rapid Marijuana (THC) Test Strip 20 and Rapid Marijuana (THC) Test Dipcard 20 is a rapid, screening test for the qualitative detection of Marijuana and their metabolites in human urine at the cut-off concentration of 20 ng/mL.

Rapid Marijuana (THC) Test Strip 50 and Rapid Marijuana (THC) Test Dipcard 50 is a rapid, screening test for the qualitative detection of Marijuana and their metabolites in human urine at the cut-off concentration of 50 ng/mL.

The tests contain two formats:1) Test Strip and 2) Test Dipcard. The tests are intended for in vitro diagnostics use. They are intended for over-the-counter use.

The tests provide only a preliminary result. To obtain a confirmed analytical result, a more specific alternative chemical method must be used. Gas Chromatography/Mass spectrometry (GC/MS) or Liquid chromatography/Mass spectrometry (LC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

C Special Conditions for Use Statement(s):

OTC - Over The Counter

D Special Instrument Requirements:

N/A

IV Device/System Characteristics:

A Device Description:

Rapid Marijuana (THC) Test Strip 20 (and 50) and Rapid Marijuana (THC) Test Dipcard 20 (and 50) are competitive binding, lateral flow immunochromatographic assays for qualitatively the detection of Marijuana and its metabolites at or above the cut-off concentration of 20 ng/ml (and 50ng/ml). The tests are performed without the use of an instrument.

Test Strips and Test Dipcards use identical test strips made with the same chemical formulation and manufacturing procedures.

Content of the kits: Test Strip (one test in one pouch), Desiccant (for storage purposes only), Leaflet with instructions for use, Urine Cup (optional), Labeled Vial (optional), Plastic Bag (optional), Mailing Box (optional)

B Principle of Operation:

Rapid Marijuana (THC) Test Strip 20 (and 50) and Rapid Marijuana (THC) Test Dipcard 20 (and 50) are competitive binding, lateral flow immunochromatographic assays that are used to screen for the presence of Marijuana and its metabolites at or above the cut-off concentration of 20 (or 50) ng/mL in urine. The tests are performed without the use of an instrument.
When the absorbent end of the test device is immersed into the urine sample, the urine is absorbed into the device by capillary action, mixes with the antibody-dye conjugate, and flows across the pre-coated membrane, in which Marijuana antigen is coated respectively.

When Marijuana and its metabolites level are at or above 20ng/ml or 50ng/ml (the cutoff), the drugs in the sample bind to the antibody-dye conjugate preventing the antibody-dye conjugate from binding to the drug-protein conjugate immobilized in the Test Regions (T) of the device. This prevents the development of a distinct colored band in the test region (T), indicating a positive result.

When Marijuana and its metabolites levels are below 20ng/ml or 50ng/ml, antibody-dye conjugate binds to the drug-protein conjugate immobilized in the Test Region (T) of the device. This produces a colored band in the test region (T) which indicates a negative result.

To serve as a procedure control, a colored line will appear at the Control Region (C), if the test has been performed properly.

V Substantial Equivalence Information:

A Predicate Device Name(s):
BIOEASY Marijuana Test Dip Card 40, BIOEASY Marijuana Test Dip Card 20, BIOEASY Marijuana Test Strip 40, BIOEASY Marijuana Test Strip 20

B Predicate 510(k) Number(s):
K192515

C Comparison with Predicate(s):

Device & Predicate Device(s):	K232732	K192515
Device Trade Name	Rapid Marijuana (THC) Test Strip 20 Rapid Marijuana (THC) Test Dipcard 20 Rapid Marijuana (THC) Test Strip 50 Rapid Marijuana (THC) Test Dipcard 50	BIOEASY Marijuana Test Dip Card 20 BIOEASY Marijuana Test Strip 20 BIOEASY Marijuana Test Dip Card 40 BIOEASY Marijuana Test Strip 40
General Device Characteristic Similarities		
Intended Use/Indications For Use	Qualitative detection of Marijuana in urine	Same
Specimen type	Human urine	Same
Methodology	Competitive binding, lateral flow	Same

	immunochromatographic assays based on the principle of antigen antibody immunochemistry	
General Device Characteristic Differences		
Calibrator and Cutoff Values	Marijuana (THC) 20 ng/mL or 50 ng/mL	Marijuana (THC) 20 ng/ml or 40 ng/ml
End user environment	Over-the-counter use	Prescription use

VI Standards/Guidance Documents Referenced:

None

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Precision studies were performed using 3 lots each of test Strip and test Dipcard. Drug free specimens were spiked with target drug (-)-11-nor-9-Carboxy-Δ9-THC at 0, ±75% cutoff, ±50% cutoff, ±25% cutoff and +100% cutoff of drug. The concentrations of the target drugs were confirmed with LC/MS. Each concentration of the urine specimen was divided into aliquots. Separate sets of blinded coded samples were assigned and randomized prior to testing. The study was conducted by 6 operators at 3 Point-of-Care sites. Two operators per location tested 3 aliquots at each concentration for each lot per day (3 runs/day) for 10 non-consecutive days using one device lot per location. One operator tested the test strip format and the second operator tested the test dipcard format. There were 1620 observations by 3 sites at 9 concentrations.

Rapid Marijuana (THC) Test Strip 20:

Approximate concentration of sample	% of cutoff	Number of determinations per lot	Result					
			Lot 1		Lot 2		Lot 3	
			Positive	Negative	Positive	Negative	Positive	Negative
0ng/ml	Negative	60	0	60	0	60	0	60
5ng/ml	-75%cutoff	60	0	60	0	60	0	60
10ng/ml	-50%cutoff	60	0	60	0	60	0	60
15ng/ml	-25%cutoff	60	6	54	4	56	4	56
20ng/ml	cutoff	60	34	26	36	24	32	28

25ng/ml	+25%cutoff	6	54	6	56	4	58	2
30ng/ml	+50%cutoff	60	60	0	60	0	60	0
35ng/ml	+75%cutoff	60	60	0	60	0	60	0
40ng/ml	+100% cutoff	60	60	0	60	0	60	0

Rapid Marijuana (THC) Test Dipcard 20:

Approximate concentration of sample	% of cutoff	Number of determinations per lot	Result					
			Lot 1		Lot 2		Lot 3	
			Positive	Negative	Positive	Negative	Positive	Negative
0ng/ml	Negative	60	0	60	0	60	0	60
5ng/ml	-75%cutoff	60	0	60	0	60	0	60
10ng/ml	-50%cutoff	60	0	60	0	60	0	60
15ng/ml	-25%cutoff	60	4	56	6	54	4	56
20ng/ml	cutoff	60	36	24	38	22	34	26
25ng/ml	+25%cutoff	60	56	4	56	4	58	2
30ng/ml	+50%cutoff	60	60	0	60	0	60	0
35ng/ml	+75%cutoff	60	60	0	60	0	60	0
40ng/ml	+100% cutoff	60	60	0	60	0	60	0

Rapid Marijuana (THC) Test Strip 50:

Approximate concentration of sample	% of cutoff	Number of determinations per lot	Result					
			Lot 1		Lot 2		Lot 3	
			Positive	Negative	Positive	Negative	Positive	Negative
0ng/ml	Negative	60	0	60	0	60	0	60
12.5ng/ml	-75%cutoff	60	0	60	0	60	0	60
25ng/ml	-50%cutoff	60	0	60	0	60	0	60
37.5ng/ml	-25%cutoff	60	4	56	6	54	2	58
50ng/ml	cutoff	60	36	24	38	22	34	26
62.5ng/ml	+25%cutoff	6	56	4	56	4	58	2
75ng/ml	+50%cutoff	60	60	0	60	0	60	0
87.5ng/ml	+75%cutoff	60	60	0	60	0	60	0
100ng/ml	+100% cutoff	60	60	0	60	0	60	0

Rapid Marijuana (THC) Test Dipcard 50:

Approximate concentration of sample	% of cutoff	Number of determinations per lot	Result					
			Lot 1		Lot 2		Lot 3	
			Positive	Negative	Positive	Negative	Positive	Negative
0ng/ml	Negative	60	0	60	0	60	0	60
12.5ng/ml	-75%cutoff	60	0	60	0	60	0	60
25ng/ml	-50%cutoff	60	0	60	0	60	0	60
37.5ng/ml	-25%cutoff	60	6	54	2	58	6	54
50ng/ml	cutoff	60	38	22	34	26	36	24
62.5ng/ml	+25%cutoff	60	58	2	56	4	54	6
75ng/ml	+50%cutoff	60	60	0	60	0	60	0
87.5ng/ml	+75%cutoff	60	60	0	60	0	60	0
100ng/ml	+100%cutoff	60	60	0	60	0	60	0

2. Linearity:

Not applicable, this device is intended for qualitative use only.

3. Analytical Specificity/Interference:

Cross-Reactivity:

To determine cross-reactivity, drug metabolites and structurally similar compounds were tested. All the components were added to drug-free normal human urine. Each sample was tested in 3 replicates using 3 lots of the test Strip and Dip Cards (for the 20ng/ml and 50ng/ml cut-ff concentrations). If any positive result was observed, the compounds were further diluted with known drug-free urine specimen sequentially to different concentrations and tested in quintuplicate, until the highest concentration that generated a negative result was reached. The cross-reacting substances with the lowest concentration that produced a positive result for each cutoff was identified and is listed in the tables below (results were the same for test strip and dipcard device formats):

Rapid Marijuana (THC) Test Strip 20 and Rapid Marijuana (THC) Dip Card 20

Compound	Quantity equivalent to cutoff(ng/mL)	% Cross-Reactivity
11-nor-Δ9-THC-9-COOH	20	100%
11-nor-Δ^8-THC-9-COOH	20	100%

Δ^9-THC	6000	0.3%
Δ^8-THC	4000	0.5%
Cannabinol	8000	0.3%
Cannabidiol	>100000	Not detected
11-Nor- Δ9-THC-carboxy glucuronide	30	66.7%
11-Hydroxy- Δ9-Tetrahydrocannabinol	20	100%
(-)-11-nor-9-carboxy-Δ 9-THC	20	100%

Rapid Marijuana (THC) Test Strip 50 and Rapid Marijuana (THC) Dip Card 50

Compound	Quantity equivalent to cutoff(ng/mL)	% Cross-Reactivity
11-nor-Δ9-THC-9-COOH	50	100%
11-nor-Δ^8-THC-9-COOH	50	100%
Δ^9-THC	10,000	0.3%
Δ^8-THC	15,000	0.5%
Cannabinol	20,000	0.3%
Cannabidiol	>100000	Not detected
11-Nor- Δ 9-THC-carboxy glucuronide	75	66.7%
11-Hydroxy- Δ 9-Tetrahydrocannabinol	50	100%
(-)-11-nor-9-carboxy-Δ 9-THC	50	100%

Interfering substances:

To determine the interference, potentially interfering substances were added to drug-free urine and target drugs urine with concentrations at 50% below and 50% above Cut-Off levels. These urine samples were tested using three batches of each of the four devices (20ng/ml cut-off Strip and Dip Card & 50ng/ml Strip and Dip Card). Compounds that showed no interference at a concentration of 100µg/mL (albumin was tested at 100 mg/dL and ethanol was tested at 1%) are summarized in the list below. There were no differences observed for both the strip and dip card formats at the two different cut-offs.

Acetaminophen, Acetophenetidin, Amoxicillin, Ampicillin, Aspirin, Atenolol, Atorvastatin, Azlocillin, Benzilic acid, Benzylpenicillin, Benzoic acid, Bilirubin, Benzydamine, Caffeine, Carbamazepine, Cephalexin, Chloralhydrate, Chloramphenicol, Chlorothiazide, Chlorpheniramine, d,l-Chlorpromazine, Cholesterol, Clonidine, Cimetidine, Citalopram, Cortisone, Creatinine , Deoxycorticosterone, Dexamethasone, Dextromethorphan, Diclofenac, Diflunisal, Digoxin, Diphenhydramine, Ephedrine, β- Estradiol, Estrone-3-sulfate, Ethyl-p-aminobenzoate, Erythromycin, Fenoprofen, Flucloxacillin, Fluoxetine, Furosemide, Gentisic acid, Hemoglobin, Hydralazine, Hydrochlorothiazide, Hydrocortisone, o-Hydroxyhippuric acid, p-Hydroxytyramine, Ibuprofen, Indomethacin, Iproniazid, d,l-Isoproterenol, Isoxsuprine, Ketamine, Ketoprofen, Labetalol, Lisinopril, Loperamide, Meperidine, Meprobamate, Methoxyphenamine, Methylphenidate, Nadolol, Nalidixic acid, Naproxen, Niacinamide, Nicotine, Nifedipine, Norethindrone, Noscapine, d,l-Octopamine, Oxalic acid, Oxolinic acid, Oxymetazoline, Oxytetracycline, Papaverine, Penicillin-G, Pentazocine, Perphenazine, Phenelzine, Prednisolone, Prednisone, d,l-Propanolol, d-Pseudoephedrine, Quinacrine, Quinine, Quindine, Ranitidine, Salicylic acid, Serotonin, Sulfamethazine, Sulindac, Tetracycline, Tetrahydrozoline, Thiamine, Thioridazine, d, l- Thyroxine, Tolbutamine, Tolbutamide, Trifluoperazine, Tryptamine, Uric acid, Verapamil, Zomepirac

The results demonstrate that all above compounds show no interference with the Rapid Marijuana Test devices of the two different cut-offs and the two different formats.

Effect of Urinary Specific Gravity

The specific gravity studies were conducted on different specific gravity including 1.000, 1.010, 1.020, 1.030, 1.040 specimens with drug free urine containing (-)-11-nor-9-Carboxy- Δ9-THC at 25ng/ml (50% below cutoff) and 75ng/ml (50% above cutoff) and 10ng/ml (50% below cutoff) and 30ng/ml (50% above cutoff). All concentrations were confirmed with LC/MS. Each sample was tested using two lots for each of the four devices (20ng/ml cut-off Strip and Dip Card & 50ng/ml Strip and Dip Card). The results demonstrate that the tested range of specific gravity does not affect the test result.

Effect of Urinary pH

The pH of an aliquot negative urine pool is adjusted to a pH range of 3 to 9 in 1 pH unit increments and spiked with (-)-11-nor-9-Carboxy-Δ9-THC at 25ng/ml (50% below cutoff) and 75ng/ml (50% above cutoff) and 10ng/ml (50% below cutoff) and 30ng/ml (50% above cutoff). All concentrations were confirmed with LC/MS. Each sample was tested using two lots of the for each of the four devices (20ng/ml cut-off Strip and Dip Card & 50ng/ml Strip and Dip Card). The result demonstrate that the tested pH range does not interfere with the performance of the test.

4. Assay Reportable Range:

Not applicable, this device is intended for qualitative use only.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

The device is traceable to commercially available reference materials.

6. Detection Limit:

Not applicable

7. Assay Cut-Off:

Analytical performance of the device around the claimed cutoff is described in the precision section VII.A1. above.

B Comparison Studies:

1. Method Comparison with Predicate Device:

Eighty (80) clinical urine samples were collected from three hospitals/drug relief reformatories. The study was conducted by 6 nurses at three Point-of-Care sites and each site conducted one lot test Strip and Dip Card for both the Rapid Marijuana (THC) Test 50 cutoff and the Rapid Marijuana (THC) Test 20 cutoff. Each sample in both studies was divided into 6 individuals. All aliquots were blindly labeled by a nonparticipant. Samples were also randomized prior to testing.

Rapid Marijuana (THC) Test 50 cut-off

Each participant only tested one format of Rapid Marijuana (THC) Test 50, one tested with strip format another tested with Dip Card. All samples were unaltered clinical specimens, and the concentrations were confirmed with LC/MS.

Rapid Marijuana (THC) Test 20 cut-off

Each participant only tested one format of Rapid Marijuana (THC) Test 20, one tested with strip format another tested with Dip Card. All the samples were unaltered clinical specimens, and the concentrations were confirmed with LC/MS.

Comparison data of Rapid Marijuana (THC) Test Strip 20

Test Strip		LC/MS					Total
		Neg. (drug free)	Neg. (<50% cutoff)	Near cutoff neg. (-50% cutoff to cutoff)	Near cutoff pos. (cutoff to +50% cutoff)	Pos. (>+50% cutoff)	
Lot 1	Positive	0	0	1	8	31	80
	Negative	27	5	7	1	0	
Lot 2	Positive	0	0	1	8	31	80
	Negative	27	5	7	1	0	
Lot 3	Positive	0	0	1	8	31	80
	Negative	27	5	7	1	0	

Comparison data of Rapid Marijuana (THC) Test Dipcard 20

Dip Card		LC/MS					Total
		Neg. (drug free)	Neg. (<50% cutoff)	Near cutoff neg. (-50% cutoff to cutoff)	Near cutoff pos. (cutoff to +50% cutoff)	Pos. (>+50% cutoff)	
Lot 1	Positive	0	0	1	8	31	80
	Negative	27	5	7	1	0	
Lot 2	Positive	0	0	1	8	31	80
	Negative	27	5	7	1	0	
Lot 3	Positive	0	0	1	8	31	80
	Negative	27	5	7	1	0	

Comparison data of Rapid Marijuana (THC) Test Strip 50

Test Strip		LC/MS					Total
		Neg. (drug free)	Neg. (<50% cutoff)	Near cutoff neg. (-50% cutoff to cutoff)	Near cutoff pos. (cutoff to +50% cutoff)	Pos. (>+50% cutoff)	
Lot 1	Positive	0	0	1	9	30	80
	Negative	21	10	8	1	0	
Lot 2	Positive	0	0	1	9	30	80
	Negative	21	10	8	1	0	
Lot 3	Positive	0	0	1	9	30	80
	Negative	21	10	8	1	0	

Comparison data of Rapid Marijuana (THC) Test Dipcard 50

Dip Card		LC/MS					Total
		Neg. (drug free)	Neg. (<50% cutoff)	Near cutoff neg. (-50% cutoff to cutoff)	Near cutoff pos. (cutoff to +50% cutoff)	Pos. (>+50% cutoff)	
Lot 1	Positive	0	0	1	9	30	80
	Negative	21	10	8	1	0	
Lot 2	Positive	0	0	1	9	30	

	Negative	21	10	8	1	0	80
Lot 3	Positive	0	0	1	9	30	80
	Negative	21	10	8	1	0	

2. Lay User Study (Home Use Consumer Study)

Specimens:
THC 20ng/ml cut-off: Drug free specimens spiked with the (-)-11-nor-9-Carboxy-Δ9-THC at different concentrations containing 0 ng/ml, 10 ng/ml, 15 ng/ml, 25 ng/ml, 30 ng/ml, 40 ng/ml. All concentrations were confirmed with LC/MS.

THC 50ng/ml cut-off: Drug free specimens spiked with the (-)-11-nor-9-Carboxy-Δ9-THC at different concentrations containing 0 ng/ml, 25 ng/ml, 37.5 ng/ml, 62.5 ng/ml, 75 ng/ml, 100 ng/ml. All concentrations were confirmed with LC/MS.

For both the THC20 and THC 50, each concentration urine specimens were divided into 60 individual containers for a total of 360 aliquots. All concentrations were confirmed with LC/MS. All aliquots were blindly labeled by a nonparticipant. Samples were also randomized prior to testing. The study was conducted at three sites. Ages from 18 to 65 participated in the study. None of the subjects had experience with a point of care drug testing product and were untrained operators. The study included two cohorts of 360-lay-users (a total of 720 lay-users) with no experience using this product. One cohort tested the 20ng/mL device and the other cohort of 360 tested the 50ng.mL device. Both cohorts of 360 lay-users were further divided into two groups; one tested with strip format, the other tested with dipcard format. Each participant was provided with the English package insert, 1 blind labeled sample, and a device. Each participant performed only 1 test on provided specimen with one format of Rapid Marijuana (THC) Test 20ng/mL or 50ng/mL (strip or dipcard) using the English package insert as guide to perform the test. They were asked to fill out an English questionnaire after finishing the test, 360 test results for a total of 6 drug concentration levels were obtained from the Home Use Consumer Study for each test (20ng/mL and 50ng/mL).

Results for both THC 20 and THC 50 are shown below:

Home Use Consumer Studies date of Rapid Marijuana (THC) Test Strip 20:

Approximate concentration of sample	% of cutoff	Number of determinations per lot	Test Strip		Agreement (%)
			Positive	Negative	
0ng/ml	Negative	30	0	30	100%
10ng/ml	-50%cutoff	30	0	30	100%
15ng/ml	-25%cutoff	30	2	28	93%
25ng/ml	+25%cutoff	30	27	3	90%
30ng/ml	+50%cutoff	30	30	0	100%
40ng/ml	+100%cutoff	30	30	0	100%

Home Use Consumer Studies date of Rapid Marijuana (THC) Test Dipcard 20:

Approximate concentration of sample	% of cutoff	Number of determinations per lot	Test Dipcard		Agreement (%)
			Positive	Negative	
0ng/ml	Negative	30	0	30	100%
10ng/ml	-50%cutoff	30	0	30	100%
15ng/ml	-25%cutoff	30	3	27	90%
25ng/ml	+25%cutoff	30	28	2	93%
30ng/ml	+50%cutoff	30	30	0	100%
40ng/ml	+100%cutoff	30	30	0	100%

Home Use Consumer Studies date of Rapid Marijuana (THC) Test Strip 50:

Approximate concentration of sample	% of cutoff	Number of determinations per lot	Test Strip		Agreement (%)
			Positive	Negative	
0ng/ml	Negative	30	0	30	100%
25ng/ml	-50%cutoff	30	0	30	100%
37.5ng/ml	-25%cutoff	30	1	29	97%
62.5ng/ml	+25%cutoff	30	28	2	93%
75ng/ml	+50%cutoff	30	30	0	100%
100ng/ml	+100%cutoff	30	30	0	100%

Home Use Consumer Studies date of Rapid Marijuana (THC) Test Dipcard 50:

Approximate concentration of sample	% of cutoff	Number of determinations per lot	Test Dipcard		Agreement (%)
			Positive	Negative	
0ng/ml	Negative	30	0	30	100%
25ng/ml	-50%cutoff	30	0	30	100%
37.5ng/ml	-25%cutoff	30	2	28	93%
62.5ng/ml	+25%cutoff	30	28	2	93%
75ng/ml	+50%cutoff	30	30	0	100%
100ng/ml	+100%cutoff	30	30	0	100%

3. Stability of the test line (Read time)

Rapid Marijuana (THC) Test Strip 20 and Test Dipcard 20
Three drug free specimens were spiked with the (-)-11-nor-9-Carboxy-Δ9-THC concentrations at 10ng/ml, 30ng/ml and 40ng/ml. All concentrations were confirmed with LC/MS. Spiked specimens and five drug free specimens (N1-N5) were tested in replicates of ten following the procedures in the package inserts.

Rapid Marijuana (THC) Test Strip 50 and Test Dipcard 50
Three drug free specimens spiked with the (-)-11-nor-9-Carboxy-Δ9-THC concentrations at 25ng/ml, 75ng/ml and 100ng/ml. All concentrations were confirmed with LC/MS. Spiked specimens and five drug free specimens (N1-N5) were tested in replicates of ten following the procedures in the package inserts.

The study supported the sponsor's claimed read time of 5 to 30 minutes.

4. Matrix Comparison:
Not applicable. This device is intended to be used with urine samples only.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Not applicable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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