

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION MEMORANDUM**

**A. 510(k) Number:**

K173792

**B. Purpose for Submission:**

Addition of previously cleared assays (EliA PR3<sup>S</sup>, MPO<sup>S</sup>, GBM) to the Phadia 2500/5000 instrument platform

**C. Measurands:**

Human serum IgG autoantibodies to serine proteinase 3 (PR3), myeloperoxidase (MPO), and glomerular basement membrane antigen (GBM)

**D. Type of Test:**

Automated semi-quantitative solid-phase fluoroimmunoassay

**E. Applicant:**

Phadia US, Inc.

**F. Proprietary and Established Names:**

EliA PR3<sup>S</sup> Immunoassay  
EliA MPO<sup>S</sup> Immunoassay  
EliA GBM Immunoassay

**G. Regulatory Information:**

1. Regulation section:

21 CFR §866.5660 – Multiple autoantibodies immunological test system

2. Classification:

Class II

3. Product codes:

**MOB**, Test System, Antineutrophil Cytoplasmic Antibodies (ANCA)  
**MVJ**, Devices, Measure, Antibodies to Glomerular Basement Membrane (GBM)

4. Panel:

Immunology (82)

**H. Intended Use:**

1. Intended uses:

EliA PR3<sup>S</sup> is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to proteinase 3 (PR3) in human serum and plasma (Li-heparin, EDTA) as an aid in the clinical diagnosis of Granulomatosis with Polyangiitis (GPA, formerly called Wegener's Granulomatosis) in conjunction with other laboratory and clinical findings. EliA PR3<sup>S</sup> uses the EliA IgG method on the instrument Phadia 2500/5000.

EliA MPO<sup>S</sup> is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to myeloperoxidase (MPO) in human serum and plasma (Li-heparin, EDTA) as an aid in the clinical diagnosis of microscopic polyangiitis (MPA) in conjunction with other laboratory and clinical findings. EliA MPOs uses the EliA IgG method on the instrument Phadia 2500/5000.

EliA GBM is intended for the in vitro semi-quantitative measurement of IgG antibodies to  $\alpha 3$  chain of collagen IV in human serum and plasma (Li-heparin, EDTA) as an aid in the clinical diagnosis of Goodpasture syndrome in conjunction with other laboratory and clinical findings. EliA GBM uses the EliA IgG method on the instrument Phadia 2500/5000.

2. Indications for use:

Same as Intended uses

3. Special conditions for use statements:

For Prescription Use Only

4. Special instrument requirements:

For use on the Phadia 2500 and Phadia 5000 instruments

**I. Device Description:**

**General Description of the "EliA Test System"**

*Assay-specific reagents:*

- EliA PR3<sup>S</sup> Wells are coated with human PR3 protein – 4 carriers (12 wells each), ready to use
- EliA MPO<sup>S</sup> Wells are coated with human MPO protein – 4 carriers (12 wells each), ready to

use

- EliA GBM Wells are coated with human recombinant  $\alpha 3$  chain of collagen IV – 2 carriers (12 wells each), ready to use
- EliA ANCA/GBM Positive Control 2500/5000: Human serum containing IgG antibodies to PR3, MPO and GBM in PBS containing BSA, detergent and 0.095% sodium azide – 6 single use vials, 0.3 mL each, ready to use

*EliA Method-specific reagents:*

- EliA Sample Diluent: PBS containing BSA, detergent and 0.095% sodium azide – 6 bottles, 48 mL each, ready to use; or 6 bottles, 400 mL each, ready to use
- EliA IgG Conjugate 50 or 200:  $\beta$ -Galactosidase labeled anti-IgG (mouse monoclonal antibodies) in PBS containing BSA and 0.06% sodium azide – 6 wedge shaped bottles, 5 mL each, ready to use; or 6 wedge shaped bottles, 19 mL each, ready to use
- EliA IgG Calibrator Strips: Human IgG (0, 4, 10, 20, 100, 600  $\mu$ g/L) in PBS containing BSA, detergent and 0.095% sodium azide – 5 strips, 6 single-use vials per strip, 0.3 mL each, ready to use
- EliA IgG Curve Control Strips: Human IgG (20  $\mu$ g/L) in PBS containing BSA, detergent and 0.095% sodium azide – 5 strips, 6 single-use vials per strip, 0.3 mL each, ready to use
- EliA IgG Calibrator Well: Coated with mouse monoclonal antibodies – 4 carriers (12 wells each), ready to use.
- EliA IgG/IgM/IgA Negative Control 2500/5000: Human sera from healthy donors in PBS containing BSA, detergent and 0.095% sodium azide – 6 single-use vials, 0.3 mL each, ready to use

*General Reagents:*

- Development Solution, Stop Solution, and Washing Solution

Phadia 2500 and Phadia 5000 are identical instruments except for sample throughput. The Phadia 2500 consists of 1 process module (2 process lines), whereas Phadia 5000 consists of 2 process modules (2x2 process lines). Instrument operation is handled by onboard Instrument Software (ISW). Data output is administered by Information Data Manager (IDM). All steps of an assay are performed within a single process line. Thus, study protocols used for Phadia 2500 are also valid for Phadia 5000.

**J. Substantial Equivalence Information:**

1. Predicate device names:

EliA PR3<sup>S</sup>, EliA MPO<sup>S</sup>, and EliA GBM on Phadia 250

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

K140225

3. Comparison with predicate:

<b>Similarities</b>		
Item	Device (EliA PR3 <sup>S</sup> , MPO <sup>S</sup> , GBM on Phadia 2500/5000)	Predicate (EliA PR3 <sup>S</sup> , MPO <sup>S</sup> , GBM on Phadia 250)
Intended Uses	<p>EliA PR3<sup>S</sup> is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to proteinase 3 (PR3) in human serum and plasma (Li-heparin, EDTA) as an aid in the clinical diagnosis of Granulomatosis with Polyangiitis (GPA, formerly called Wegener's Granulomatosis) in conjunction with other laboratory and clinical findings. EliA PR3s uses the EliA IgG method on the instrument Phadia 2500/5000.</p> <p>EliA MPO<sup>S</sup> is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to myeloperoxidase (MPO) in human serum and plasma (Li-heparin, EDTA) as an aid in the clinical diagnosis of microscopic polyangiitis (MPA) in conjunction with other laboratory and clinical findings. EliA MPOs uses the EliA IgG method on the instrument Phadia 2500/5000.</p> <p>EliA GBM is intended for the in vitro semi-quantitative measurement of IgG antibodies to <math>\alpha</math>3 chain of collagen IV in human serum and plasma (Li-heparin, EDTA) as an aid in the clinical diagnosis of Goodpasture syndrome in conjunction with other laboratory and clinical findings. EliA GBM uses the EliA IgG method on the instrument Phadia 2500/5000.</p>	Same
Assay Type	Solid-phase fluoroimmunoassay	same

<b>Similarities</b>		
Item	Device (EliA PR3 <sup>S</sup> , MPO <sup>S</sup> , GBM on Phadia 2500/5000)	Predicate (EliA PR3 <sup>S</sup> , MPO <sup>S</sup> , GBM on Phadia 250)
Quantitation	Semi-quantitative, arbitrary units	same
Measurands	Autoantibodies to: serine proteinase 3 (PR3) myeloperoxidase (MPO) collagen IV- $\alpha_3$ (GBM)	same
Component set	Antigen-coated wells, 6-point IgG calibrator strip, IgG calibrator wells, IgG control, conjugate, diluent, wash buffer, development solution, stop solution	same
Temperature (incubation)	37°C	same
Calibration	EliA 6-point total human IgG calibration	same
Calibration Frequency	28 days	same
Conjugate (Detection antibody)	$\beta$ -Galactosidase labeled monoclonal mouse anti-human IgG	same
Detection substrate	0.01% 4-Methylumbelliferyl- $\beta$ -D-galactoside (MUG)	same
Calibrators	6 point, total IgG	
Sample dilution	PR3: 1:100 MPO: 1:50 GBM: 1:100	same
Input sample volume	90 $\mu$ L diluted 20 $\mu$ L undiluted (for automated dilution)	same
Reagent Stability: Onboard Storage	2–8°C: EliA well carriers (28 days) Room Temperature: sample diluent (7 days), wash buffer (7 days), wash concentrate (6 months)	same
Assay cutoff/interpretation	PR3 <sup>S</sup> : Negative: <2.0 U/mL Equivocal: 2.0 – 3.0 U/mL Positive: >3.0 U/mL MPO <sup>S</sup> : Negative: <3.5 U/mL Equivocal: 3.5 – 5.0 U/mL Positive: >5.0 U/mL GBM: Negative: <7.0 U/mL	same

<b>Similarities</b>		
Item	Device (EliA PR3 <sup>S</sup> , MPO <sup>S</sup> , GBM on Phadia 2500/5000)	Predicate (EliA PR3 <sup>S</sup> , MPO <sup>S</sup> , GBM on Phadia 250)
	Equivocal: 7.0–10.0 U/mL Positive: >10.0 U/mL	

<b>Differences</b>		
Item	Device (EliA PR3 <sup>S</sup> , MPO <sup>S</sup> , GBM on Phadia 2500/5000)	Predicate (EliA PR3 <sup>S</sup> , MPO <sup>S</sup> , GBM on Phadia 250)
Instrument Platform	Phadia 2500 Phadia 5000	Phadia 250
Matrix	Serum, plasma (Li-heparin, EDTA)	Serum, plasma (Li-heparin, EDTA, citrate)
Reagent Stability: Onboard storage	2-8°C: Conjugate (7 days) Room Temperature: Development Solution (5 days), Stop Solution (14 days)	Conjugate: single use Room Temperature: Development solution (40 hours), Stop Solution (7 days)
Reagent reuse	Disposable dilution equipment	Conjugate should not be reused due to risk of carryover contamination
Daily Sample Throughput	Ph2500: ~2500 tests/day Ph5000: ~5000 tests/day	~250 tests/day

#### **K. Standard/Guidance Documents Referenced:**

Org	Standard ID	Version	Title
CLSI	EP05	A3	Evaluation of Precision Performance of Quantitative Measurement Methods
CLSI	EP06	A	Evaluation of the Linearity of Quantitative Measurement Procedures
CLSI	EP09	A3	Measurement Procedure Comparison and Bias Estimation Using Patient Samples
CLSI	EP17	A	Protocols for Determination of Limits of Detection and Limits of Quantification

#### **L. Test Principle:**

EliA tests are fluorescence immunoassays for the detection and measurement of human antibodies based on EliA solid-phase components, which contain specific antigens for the antibodies to be measured. EliA uses a modular reagent system. The test specific, method specific, and general reagents are packaged and purchased as separate units.

**EliA ANCA/GBM:** Polystyrene EliA wells are coated with the respective target antigens: human

PR3, human MPO, or human recombinant collagen IV $\alpha$ 3 (the glomerular basement membrane [GBM] antigen). Together, this grouping of autoantigenic targets comprise the ANCA/GBM. If present in the patient's specimen, autoantibodies to these proteins bind to the specific antigen. After washing away unbound antibodies, enzyme-labeled antibodies against human IgG antibodies (EliA IgG Conjugate) are added to form an antibody-conjugate complex. After incubation, non-bound conjugate is washed away and the bound complex is incubated with a fluorogenic development solution. After stopping the reaction, the fluorescence in the reaction mixture is measured. The higher the response value, the more autoantigen-specific IgG is present in the specimen. To evaluate test results, the response for patient samples is compared directly to the response for calibrators.

**Phadia 2500/5000:** The Phadia 2500 and Phadia 5000 instruments are automated platforms for EliA test procedures from sample and reagent handling up to processing of results.

**M. Performance Characteristics:**

1. Analytical performance:

All results presented below met the Manufacturer's pre-determined acceptance criteria for all analytical performance studies.

a. *Precision/Reproducibility:*

The sponsor modeled Precision studies based on CLSI EP05-A3.

To determine the precision of the assay, variability was assessed in a study with a total of four replicates/sample  $\times$  three instruments  $\times$  seven days  $\times$  one run/day for a total of 84 datapoints per sample, with a calibration curve for each run. For each assay (PR3<sup>S</sup>, MPO<sup>S</sup>, GBM), five samples were tested: one negative, two in the equivocal range for each analyte, and two positive specimens. Calibration on day 1 was applied to all data to model normal operations.

EliA PR3 <sup>S</sup> Precision on Phadia 2500/5000 – across instruments									
Mean (U/mL)	n	Within-Run		Between-Run		Between-Instrument		Total Imprecision	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV
1.6	84	0.1	7.7	0.1	4.6	0.1	4.1	0.2	9.9
2.3	84	0.1	5.0	0.1	6.3	0.0	0.0	0.2	8.0
2.7	84	0.1	3.8	0.1	4.8	0.2	6.1	0.2	8.6
70.0	84	2.6	3.7	3.0	4.4	1.5	2.2	4.3	6.1
170.0	84	8.3	4.9	9.1	5.4	4.1	2.4	13.0	7.7

For individual Phadia 2500/5000 instruments, total imprecision was  $\leq 10\%$  CV for all samples tested with the EliA PR3<sup>S</sup> assay.

EliA MPO <sup>S</sup> Precision on Phadia 2500/5000 – across instruments									
Mean (U/mL)	n	Within-Run		Between-Run		Between-Instrument		Total Imprecision	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV
1.3	84	0.1	5.5	0.0	3.3	0.1	4.7	0.1	8.0
3.6	84	0.2	4.2	0.2	4.4	0.1	3.9	0.3	7.3
4.9	84	0.3	5.2	0.3	6.2	0.2	4.8	0.5	9.4
71.5	84	3.4	4.7	3.8	5.3	4.8	6.7	7.0	9.7
117.8	84	5.4	4.6	6.5	5.5	7.0	5.9	11.0	9.3

For individual Phadia 2500/5000 instruments, total imprecision was <10% CV for all samples tested with the EliA MPO<sup>S</sup> assay.

EliA GBM Precision on Phadia 2500/5000 – across instruments									
Mean (U/mL)	n	Within-Run		Between-Run		Between-Instrument		Total Imprecision	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV
4.0	84	0.4	10.0	0.3	8.0	0.6	14.8	0.8	19.5
7.8	84	0.5	6.0	0.5	6.2	0.3	4.2	0.7	9.6
9.6	84	0.4	3.7	0.4	4.7	0.0	0.4	0.6	6.0
191.0	84	6.7	3.5	12.4	6.5	3.5	1.8	14.5	7.6
522.0	84	22.2	4.2	25.4	4.9	0.0	0.0	33.7	6.5

For individual Phadia 2500/5000 instruments, total imprecision was <20% CV for all samples tested with the EliA GBM<sup>S</sup> assay.

The lot-to-lot imprecision study and data were in K140225.

b. *Linearity/assay reportable range:*

The sponsor modeled Linearity studies based on CLSI EP06-A.

Four patient serum samples were diluted in sample diluent and tested with one lot of EliA PR3<sup>S</sup>, MPO<sup>S</sup>, and GBM reagents and one set of system reagents on Phadia 2500/5000. The ratios of observed/expected values were calculated.

EliA PR3 <sup>S</sup> Linearity on Phadia 2500/5000			
Dilution range (U/mL)	Slope	Intercept	R <sup>2</sup>
0.7 – 22.9	1.02 (0.97–1.07)	0.30 (-0.15–0.75)	1.00
1.3 – 106.9	0.99 (0.98–1.01)	0.24 (-0.44–0.91)	1.00
1.4 – 125.9	1.00 (0.99–1.01)	-0.09 (-0.54–0.37)	1.00
2.0 – 203.5	1.00 (0.98–1.03)	-1.88 (-3.52– -0.25)	1.00

The linear range and the measuring range for EliA PR3<sup>S</sup> are set to 1.0 U/mL (LoQ) to 177 U/mL (upper limit of measuring range). The reportable range for EliA PR3<sup>S</sup> is set

to 0.6 U/mL (LoD) to 177 U/mL (upper limit of measuring range). The sponsor notes in the product insert: “Please note that concentration values between LoD and LoQ may show a higher uncertainty.”

EliA MPO <sup>S</sup> Linearity on Phadia 2500/5000			
Dilution range (U/mL)	Slope	Intercept	R <sup>2</sup>
0.2 – 8.7	1.01 (0.99–1.03)	0.01 (-0.07–0.09)	1.00
0.5 – 8.2	1.01 (0.98–1.03)	0.00 (-0.09–0.09)	1.00
0.2 – 10.3	0.99 (0.96–1.03)	0.13 (-0.03–0.28)	1.00
1.8 – 143.2	1.01 (1.00–1.02)	0.07 (-0.67–0.80)	1.00

The linear range and the measuring range for EliA MPO<sup>S</sup> are set to 0.3 U/mL (LoQ) to 134 U/mL (upper limit of measuring range). The reporting range for EliA MPO<sup>S</sup> is set to 0.2 U/mL (LoD) to 134 U/mL (upper limit of measuring range). The sponsor notes in the product insert: “Please note that concentration values between LoD and LoQ may show a higher uncertainty.”

EliA GBM Linearity on Phadia 2500/5000			
Dilution range (U/mL)	Slope	Intercept	R <sup>2</sup>
8.1 – 527.3	1.04 (0.98–1.09)	-2.18 (-14.04–9.68)	1.00
1.6 – 31.5	1.00 (0.96–1.04)	-0.57 (-1.12– -0.02)	1.00
3.9 – 262.8	1.01 (0.98–1.04)	0.83 (-2.41–4.07)	1.00
222.1 – 808.8	0.95 (0.90–1.01)	52.27 (25.9–78.63)	0.99

The linear range and the measuring range for EliA GBM are set to 2.4 U/mL (LoQ) to 680 U/mL (upper limit of measuring range). The reporting range for EliA GBM is set to 1.5 U/mL (LoD) to 680 U/mL (upper limit of measuring range). The sponsor notes in the product insert: “Please note that concentration values between LoD and LoQ may show a higher uncertainty.”

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

EliA IgG calibration method and traceability was previously reviewed in K140225.

Stability was previously reviewed in K140225.

d. *Detection limit:*

The sponsor modeled Detection Capability studies based on CLSI EP17-A.

One negative serum sample and five serum samples with low antibody concentration were tested in twelve replicates in each of six runs on different days (12 replicates × one run/day × six days = 72 data points per sample). For Phadia 2500/5000, each sample was tested in a total of six runs on one Phadia 2500/5000 instrument. The results are

summarized in the tables below:

EliA Limit of Blank (LoB), Detection (LoD), and Quantitation (LoQ) on Phadia 2500/5000			
Analyte	LoB	LoD	LoQ
PR3	0.3	0.6	1.0
MPO	0.1	0.2	0.3
GBM	0.7	1.5	2.4

LoB were calculated by non-parametric method; LoD were calculated by parametric method, based on non-parametric LoB; because bias could not be reliably estimated, LoQ was calculated by precision target, based on a target precision value of 20%.

e. *Analytical specificity:*

The effect of endogenous and exogenous interferences was reviewed in K140225.

f. *Assay cut-off:*

Values derived from K140225.

EliA ANCA/GBM Assay Cutoffs on Phadia 2500/5000			
Analyte	Negative	Equivocal	Positive
PR3	<2.0	2.0 – 3.0	>3.0
MPO	<3.5	3.5 – 5.0	>5.0
GBM	<7.0	7.0 – 10.0	>10.0

2. Comparison studies:

a. *Method comparison with predicate device:*

The sponsor modeled Method Comparison studies based on CLSI EP09-A3.

Positive and Negative Percent Agreement values were calculated for each analyte, for each of three Phadia 2500/5000 instrument in comparison to a single Phadia 250 instrument.

One hundred three (103) PR3, 107 MPO, and 100 GBM samples were run in singlicate on three Phadia 2500/5000 instruments and one Phadia 250 for comparison. Comparisons for each Phadia 2500/5000 instrument against the Phadia 250 predicate instrument by Passing-Bablok linear regression method is depicted in the table, with 95% confidence intervals.

EliA Method Comparison of EliA ANCA/GBM assays on individual Phadia 2500/5000 instruments against Phadia 250 instrument (95% Confidence Intervals)

Analyte	Phadia 2500/5000 Instrument A			Phadia 2500/5000 Instrument B			Phadia 2500/5000 Instrument C		
	slope	intercept	R <sup>2</sup>	slope	intercept	R <sup>2</sup>	slope	intercept	R <sup>2</sup>
PR3	0.99 (0.94–1.03)	0.15 (-0.07–0.33)	0.99	1.00 (0.96–1.04)	0.10 (-0.07–0.28)	0.99	1.00 (0.96–1.04)	-0.01 (-0.12–0.14)	0.99
MPO	0.98 (0.95–1.00)	-0.02 (-0.27–0.09)	0.99	0.98 (0.96–1.01)	-0.02 (-0.24–0.10)	0.99	0.98 (0.96–1.01)	-0.02 (-0.24–0.10)	0.99
GBM	0.94 (0.92–0.96)	0.85 (0.56–1.21)	0.99	0.95 (0.91–0.99)	1.04 (0.73–1.39)	0.99	0.98 (0.95–1.00)	0.34 (0.04–0.63)	0.99

Per FDA Guidance, “Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic Tests”, the equivocal zone of the ANCA/GBM assays makes it appropriate to employ the recommendations in that guidance – for equivocal values to be calculated in one set of agreement measures (positive percent agreement [PPA] and negative percent agreement [NPA]) included with positive results.

EliA Method Comparison Agreement of individual Phadia 2500/5000 instruments against Phadia 250 instrument (95% Confidence Intervals), including equivocal samples considered as positive samples:

Analyte	n	Phadia 2500/5000 Instrument A		Phadia 2500/5000 Instrument B		Phadia 2500/5000 Instrument C	
		PPA	NPA	PPA	NPA	PPA	NPA
PR3	103	98.8% (93.7–99.8%)	76.5% (52.7–90.5%)	100% (95.7–100%)	76.5% (52.7–90.5%)	97.7% (91.9–99.4%)	82.4% (59.0–93.8%)
MPO	107	97.8% (92.2–99.4%)	94.4% (74.3–99.0%)	97.8% (92.2–99.4%)	100% (80.6–100%)	97.8% (92.2–99.4%)	100% (80.6–100%)
GBM	100	100% (95.5–100%)	84.2% (62.4–94.5%)	100% (95.5–100%)	84.2% (62.4–94.5%)	100% (95.5–100%)	89.5% (68.6–97.1%)

In another set of agreement measures, equivocal results were included with negative values.

EliA Method Comparison Agreement of individual Phadia 2500/5000 instruments against Phadia 250 instrument (95% Confidence Intervals), including equivocal samples considered as negative samples:

		Phadia 2500/5000 Instrument A		Phadia 2500/5000 Instrument B		Phadia 2500/5000 Instrument C	
Analyte	<i>n</i>	PPA	NPA	PPA	NPA	PPA	NPA
PR3	103	98.6% (92.5–99.8%)	96.8% (83.8–99.4%)	97.2% (90.4–99.2%)	96.8% (83.8–99.4%)	98.6% (92.5–99.8%)	93.6% (79.3–98.2%)
MPO	107	91.5% (91.2–99.3%)	100% (87.9–100%)	97.5% (91.2–99.3%)	100% (87.9–100%)	97.5% (91.2–99.3%)	100% (87.9–100%)
GBM	100	98.6% (92.6–99.8%)	92.6% (76.6–98.0%)	98.6% (92.6–99.8%)	92.6% (76.6–98.0%)	98.6% (92.6–99.8%)	100% (97.6–100%)

b. *Matrix comparison:*

Matrix comparison between serum, Li-Heparin, and EDTA plasma was demonstrated in K140225.

3. Clinical studies:

Clinical performance was previously reviewed in K140225.

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

The frequency distribution for PR3, MPO and GBM antibodies was investigated in a group of apparently healthy subjects equally distributed across age and sex, using sera from a Caucasian population obtained from a blood bank. The results are given in the table below:

Reference Ranges on Phadia 2500/5000				
Analyte	<i>n</i> =	Median (U/mL)	95 <sup>th</sup> Percentile	99 <sup>th</sup> Percentile
PR3	400	0.7	1.1	1.49
MPO	400	0.3	0.5	0.8
GBM	400	1.9	2.7	3.2

**N. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable.

**O. Conclusion:**

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