JAN 16 2014

510 (k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: k130945

1. Submitter's name, address, telephone, contact person, and the date the summary was prepared:

Submitter's Name:	Eurospital S.p.A.
Submitter's Address:	Via Flavia, 122 34147 Trieste Italy
Submitter's Telephone Number:	Tel. +39 0408997269
Submitter's Contact Name:	Dr. Claudio G. Frattini, Technical Director
Date of 510(k) Preparation:	February 29, 2013

2. Name of the device, including the trade or proprietary name, the common or usual name and the classification name:

Proprietary Name:	CALPREST®
Common Name:	Fecal calprotectin immunological test system
Classification Name:	Calprotectin, Fecal; 21 CFR 866.5180; Class II Product Code: NXO

3. Identification of the legally marketed device to which the submitter claims substantial equivalence:

Predicate Device Name:	PhiCal™ Test 510(k) Number: K050007 Regulation Number: 21CFR866.5180 Regulation Class: Class II Distributed By: Genova Diagnostics Ashville, NC

4. Description of the device

Calprest® is an enzyme-linked immunosorbent assay (ELISA) system with colorimetric detection based on the use of polyclonal antibody against calprotectin. Calprotectin present in the diluted sample is bound by the antibody adsorbed to the surface of the plastic well. The enzyme conjugated antibody binds to the captured antigen and subsequently the enzyme catalyzes the conversion of the substrate to a colored product. The intensity of the color is proportional to the amount of conjugate bound, and thus to the amount of captured calprotectin. Concentration of calprotectin in the samples is calculated using the provided standards.

5. Statement of the intended use of the device

Device Intended Use: Calprest® is a quantitative ELISA for detecting concentration of faecal calprotectin. Calprest® can be used as an in vitro diagnostic to aid in the diagnosis of Inflammatory Bowel Diseases (IBD, Crohn's disease and ulcerative colitis) and to differentiate IBD from Irritable Bowel Syndrome (IBS) in conjunction with other clinical and laboratory findings.

6. Summary of the technological characteristics of the device

Calprest ® is identical to PhiCal™ Test in that they are manufactured by Eurospital S.p.A. Trieste, Italy. The only differences are the name of the test on the labels, the number of calibrators in the kit and the dynamic range of the assay.

7. Summary of performance characteristics

7.1 Expected Values

Calprotectin Concentration	Interpretation	Follow-Up
<15.6 - 50 mg/kg	Normal	None
50 - 120 mg/kg	Borderline	Re-evaluate at 4-6 weeks
>120 mg/kg	Abnormal	Repeat as clinically indicated

7.2 Clinical Performance

Borderline considered Positive		**IBD**		**Total**
		Positive	**Negative**	
Calprest®	**Positive**	95	6	101
	Negative	3	34	37
	Total	98	40	138
Sensitivity		**96.9%**	(95% CI 91.3% - 99.4%)[§]	
Specificity		**85.0%**	(95% CI 70.2% - 94.3%)	
PPV*		**94.1%**	(95% CI 87.5% - 97.8%)	
NPV**		**91.9%**	(95% CI 78.1% - 98.3%)	

Borderline considered Negative		**IBD**		**Total**
		Positive	**Negative**	
Calprest®	**Positive**	78	3	81
	Negative	20	37	57
	Total	98	40	138
Sensitivity		**79.6%**	(95% CI 70.3% - 87.1%)[§]	
Specificity		**92.5%**	(95% CI 79.6% - 98.4%)	
PPV*		**96.3%**	(95% CI 89.6% - 99.2%)	
NPV**		**64.9%**	(95% CI 51.1% - 77.1%)	

* PPV: Positive Predictive Value

** NPV: Negative Predictive Value

§ CI: Confidence Interval

7.3 Extraction Reproducibility

Values are reported in mg/kg

Extracted stool sample No.	1	2	3
Mean (mg/kg)	28.4	41.1	79.4
SD	3.9	3.7	5.6
% CV	13.6	8.9	7.0

7.4 Comparison

7.4.1 Device Comparison

Reagents: **Calprest®, code 9031 manufactured by Eurospital S.p.A.**

Predicate device: **PhiCal Test - FDA 510(k) – K050007 manufactured by Eurospital S.p.A.**

Similarities		
Item	**New device**	**Predicate (K050007)**
	Calprest®, code 9031	**PhiCal Test code 9053**
Intended use	to aid in the diagnosis of Inflammatory Bowel Diseases (IBD, Crohn's disease and ulcerative colitis) and to differentiate IBD from Irritable Bowel Syndrome (IBS) in conjunction with other clinical and laboratory findings.	Same
Technology	ELISA	Same
Antigen	Calprotectin	Same
Assay format	Quantitative	Same
Positive and Negative controls	Ready to use	Same
Sample type	stool	Same
Sample dilution	1:2500	Same
Incubation time	45-45-30 minutes at RT	Same
Sample volume	1-5 g stool	Same
Extraction solution	2,5x concentrate	Same
Sample buffer diluent	10x concentrate	Same
Wash buffer	20x concentrate	Same
Conjugate	Alkaline phosphatase	Same
Substrate	pNPP	Same
Platform	96 well microtiter plate	Same
OD Reading	405 nm	Same
Cut-off	50 mg/kg (µg/g)	Same

Differences		
Item	**New device .**	**Predicate (K050007)**
	Calprest®, code 9031	**PhiCal Test, code 9053**
Calibrators	6 levels: 6.25, 12.5, 25, 50, 100, 200 ng/ml	5 levels: 6.25, 12.5, 25, 50, 100 ng/ml

7.4.2 Method Comparison

Borderline Value considered as Positive				
		PhiCal™		
		Pos	Neg	
Calprest® ®	Pos	74	1	75
	Neg	4	52	56
		78	53	
Positive Agreement	**94.9%**	(95% C.I. 87.4% - 98.6%)		
Negative Agreement	**98.1%**	(95% C.I. 89.9% - 100.0%)		
Overall agreement	**96.2%**	(95% C.I. 91.3% - 98.7%)		

Borderline Value considered as Negative				
		PhiCal™		
		Pos	Neg	
Calprest® ®	Pos	43	2	45
	Neg	4	82	86
		47	84	
Positive Agreement	**91.5%**	(95% C.I. 79.6% - 97.6%)		
Negative Agreement	**97.6%**	(95% C.I. 91.7% - 99.7%)		
Overall agreement	**95.4%**	(95% C.I. 90.3% - 98.3%)		

Deming Regression Analysis (y: Calprest, x: PhiCal):

	Slope (95% CI)	Y-intercept (95% CI)
y=0.98x-1.85	0.98 (0.96 to 1.01)	-1.85 (-3.96 to 0.96)

7.5 Intra-assay Precision

Values are reported in mg/kg

Extracted stool sample No.	1	2	3	4	5	6	7	8
Mean (mg/kg)	438.7	355.2	352.9	311.7	199.9	125.7	57.8	27.7
SD	33.7	43.0	43.7	38.8	6.6	9.8	2.9	1.0
% CV	7.7	12.1	12.4	12.4	3.3	7.8	5.0	3.7

7.6 Inter-assay Precision

Values are reported in mg/kg

Extracted stool sample No.	1	2	3	4	5	6	7	8
Mean (mg/kg)	359.9	209.8	185.5	117.0	70.4	48.8	40.9	20.6
SD	27.5	17.8	17.8	9.3	6.8	4.5	3.4	2.6
% CV	7.7	8.5	9.6	8.0	9.6	9.3	8.2	12.4

7.7 Inter-lot Precision

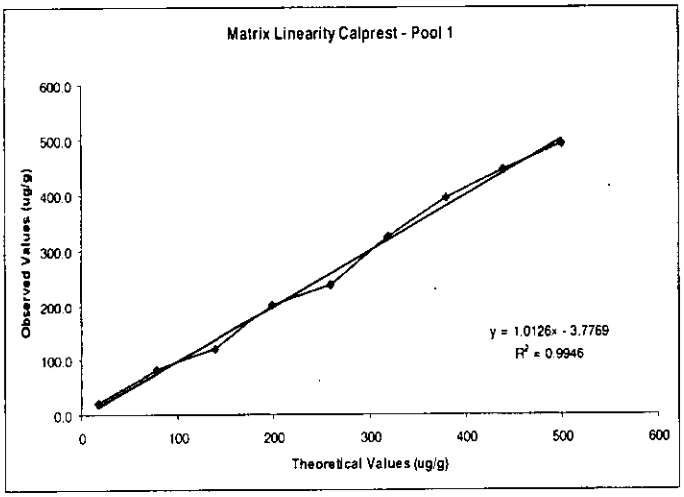
	Lot # 5637		Lot # 5888		Lot # 5488		Overall		
Extracted stool sample No	Mean (mg/kg)	%CV	Mean (mg/kg)	%CV	Mean (mg/kg)	%CV	Mean (mg/kg)	SD	%CV
1	106.1	5.2	103.2	2.8	113.9	1.3	107.7	5.779	5.4
2	63.4	4.7	60.4	2.2	65.5	6.8	63.1	3.682	5.8
3	185.0	3.5	177.7	13.3	192.6	0.8	185.1	14.545	7.9
4	44.0	2.3	43.5	4.2	43.8	3.2	43.8	1.358	3.1
5	36.5	3.9	38.2	7.3	33.2	7.2	36.0	3.001	8.3
6	354.6	13.6	340.2	13.7	340.0	12.0	344.9	42.615	12.4

7.8 Site-to-site precision

Sample#	Actual value mg/kg	Site 1 mg/kg	Site 2 mg/kg	Site 3 mg/kg	Mean (mg/kg)	St. Dev.	CV%	Delta %
G52	28.0	27.7	33.3	28.2	29.7	3.094	10.4%	106%
G44	66.0	74.1	66.7	69.4	70.1	3.770	5.4%	106%
G11	101.0	102.1	99.9	106.2	102.7	3.210	3.1%	102%
G04	160.0	157.6	169.2	161.1	162.6	5.982	3.7%	102%
G16	349.0	332.8	356.0	326.1	338.3	15.659	4.6%	97%
G54	557.0	510.8	565.6	550.4	542.2	28.255	5.2%	97%

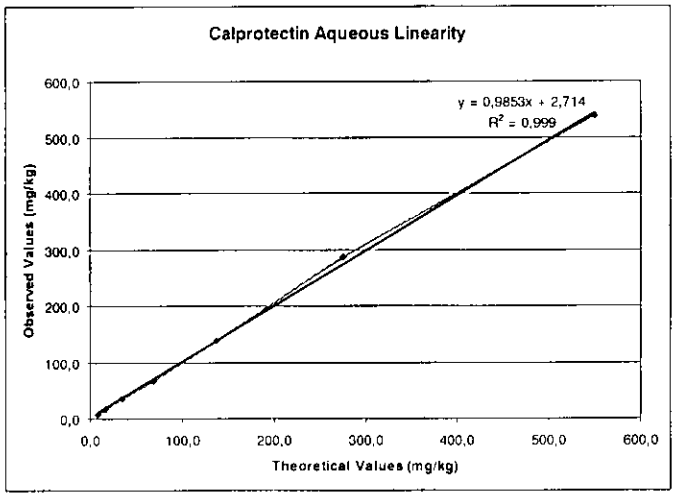
7.9 Linearity

7.9.1 Matrix Linearity



Pool No.	Test Range (µg/g)	Slope (95% CI)	Y-intercept (95% CI)	R2	% Recovery Rate (Obtained/Theoretical)
1	20.4 to 492.8	1.0126 (0.9461 to 1.079)	-3.777 (-23.85 to 16.29)	0.9946	87.0% to 113.2%

7.9.1 Aqueous Linearity



Sample No.	Test Range (µg/g)	Slope (95% CI)	Y-intercept (95% CI)	R^2	% Recovery Rate (Obtained/Theoretical)
1	8.2 to 538.5	0.9853 (0.9498 to 1.0208)	-2.7140 (-5.813 to 11.241)	0.9990	95.2% to 109.3%

7.10 Calprotectin Recovery

	Calprotectin Recovery Data							
Sample type	**Description**	**#1**	**#2**	**#3**	**#4**	**#5**	**#6**	**#7**
(a)	Baseline (mg/kg)	18.3	47.5	59.4	66.5	115.2	232.5	421.9
	Spike Value (mg/kg)	31.2	31.2	31.2	31.2	31.2	31.2	31.2
(b)	Theoretical (Base + Spike) (mg/kg)	49.6	78.8	90.6	97.8	146.6	263.7	452.1
	Observed (Base + Spike) (mg/kg)	49.8	81.1	100.1	108.7	166.0	271.3	475.0
	% Recovery	**100.5**	**103.0**	**110.5**	**111.1**	**113.4**	**102.8**	**112.6**

7.11 LoB and LoD

LoB = 3.04 mg/kg LoD = 3.98 mg/kg

7.12 Interfering Substance

A number of potential interfering foods, pharmaceutical and nutraceutical substances were tested. No interferences were observed.

Pool	No addition	Addition of bacterial suspensions – Table 1									
		E coli		*Salmonella spp*		*Shigella spp*		*Yesinia spp*		*Klebsiella spp*	
	mg/kg	mg/kg	Δ%	mg/kg	Δ%	mg/kg	Δ%	mg/kg	Δ%	mg/kg	Δ%
A	459.3	470.8	102.5	447.9	97.5	466.7	101.6	441.9	96.2	455.5	99.2
B	273.2	262.1	95.9	297.8	109.0	261.4	95.7	280.8	102.8	261.1	95.6
C	143.6	137.1	95.5	146.4	102.0	148.1	103.1	136.8	95.3	150.5	104.8
D	68.2	66.3	97.2	68.0	99.7	69.7	102.2	65.0	95.3	70.5	103.4
E	30.1	31.2	103.8	29.7	98.7	31.6	105.1	30.2	100.4	31.2	103.6

Pool	No addition	Addition of Drugs, Nutrients and Hemoglobin - Table 2a									
		Vancomycin		Ciproflaxin hcl		Vitamin E		Prevacid		Azathioprine	
	mg/kg	mg/kg	Δ%	mg/kg	Δ%	mg/kg	Δ%	mg/kg	Δ%	mg/kg	Δ%
A	468,9	467,1	99,6	479,4	102,2	457,9	97,7	453,5	96,7	468,4	99,9
B	268,1	272,9	101,8	270,9	101,0	261,0	97,4	271,2	101,2	263,4	98,2
C	145,4	141,7	97,5	140,5	96,6	140,0	96,3	144,2	99,2	143,4	98,6
D	68,8	69,1	100,4	69,2	100,6	68,8	100,0	68,2	99,1	68,5	99,6
E	31,2	32.1	97.2	32,7	104,8	32,0	99.7	32,6	104,5	32,5	104,2

Pool	No addition	Addition of Drugs, Nutrients and Hemoglobin - Table 2a									
		Pentasa		Asacol		Prednisone		Multivitamin		Hemoglobin	
	mg/kg	mg/kg	Δ%	mg/kg	Δ%	mg/kg	Δ%	mg/kg	Δ%	mg/kg	Δ%
A	468,9	461,8	98,5	461,5	98,4	446.7	95,3	478,4	102,0	473,3	100,9
B	268,1	271,1	101,1	273,5	102,0	268,6	100,2	272,2	101,5	274,7	102,5
C	145,4	150,1	103,2	138,2	95,0	138,5	95,3	146,0	100,4	146,6	100,8
D	68,8	70,7	102,8	71,0	103,2	71,1	103,3	69,2	100,6	69,6	101,2
E	31,2	32,2	103,2	31.8	99.1	32,2	103,2	30,7	98,4	31,0	99,4

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

EUROSPITAL S.P.A.
c/o MR. DAVID DUNN
CONSULTANT
3331 EAGLE WATCH DRIVE
WOODSTOCK, GA 30189

January 16, 2014

Re: K130945
Trade/Device Name: CALPREST®
Regulation Number: 21 CFR 866.5180
Regulation Name: Fecal calprotectin immunological test system
Regulatory Class: II
Product Code: NXO
Dated: December 11, 2013
Received: December 12, 2013

Dear Mr. Dunn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Leonthena R. Carrington -S

for Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K130945

Device Name
Calprest®

Indications for Use *(Describe)*

Calprest® is a quantitative ELISA for detecting the concentration of fecal calprotectin. Calprest® can be used as an in-vitro diagnostic to aid in the diagnosis of Inflammatory Bowel Diseases (IBD, Crohn's disease and ulcerative colitis) and to differentiate IBD from Irritable Bowel Syndrome (IBS) in conjunction with other clinical and other laboratory findings.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Leonthena R. Carrington -S