

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

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

K053257

**B. Purpose of Submission:**

For the detection of ova and parasites in human stool

**C. Measurand:**

Parasitic eggs, larvae, protozoa and juvenile nematodes

**D. Type of Test:**

Parasite Concentration device

**E. Applicant:**

Alpha Tec Systems, Inc.

**F. Proprietary and Established Names:**

Para-Pro™ fc50

**G. Regulatory Information:**

1. Regulation section:  
21 CFR Part 866.2900 Microbiological Specimen Collection and Transport Device
2. Classification:  
I
3. Product Code:  
LKS – Device, Parasite Concentration
4. Panel:  
83 Microbiology

**H. Intended Use:**

1. Intended use(s):  
Para-Pro™ fc50 is a unique, patent pending device for the separation of fecal debris from feces preserved in appropriate fixative reagents: 10% buffered formalin; SAF sodium acetate acetic acid formaldehyde; and Proto-fix™ CLR from the appropriate fixed/preserved specimen for the concentration of eggs, larvae, protozoa and juvenile nematodes associated with intestinal infections.

Indication(s) for use:

Para-Pro™ fc50 is a unique, patent pending device for the separation of fecal debris from the appropriate preserved specimen (10% buffered formalin; SAF sodium acetate acetic acid formaldehyde; and Proto-fix™ CLR) for the concentration of eggs, larvae, protozoa and juvenile nematodes associated with intestinal infections.

2. Special condition for use statement(s):  
For Prescription Use Only
3. Special instrument Requirements:  
Not applicable

**I. Device Description:**

Para-Pro™ fc50 is a large surface-area filtration device utilizing a 1.6 mm<sup>2</sup> opening in a cone shape to maximize the filtration area. When a fixed/preserved specimen is filtered, by gravity, through the filter device, the larger fecal debris is separated from the preserved fecal specimen. This device traps the fecal debris allowing large parasite forms to pass through the device into a collection centrifuge tube. The device is designed to accommodate a standard 30ml vial containing a suitable fixative for intestinal parasitic concentration procedures (10% buffered formalin; SAF sodium acetate acetic acid formaldehyde; and Proto-fix™ CLR), creating a completely closed system, and on the opposite end the device is attached to a collection tube consisting of a 50ml centrifuge tube and inverted to initiate the gravity filtration process.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):  
Para-Pac® Macro-CON  
Predicate K number(s):  
K860034
2. Comparison with predicate(s):

<b>Similarities</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Intended use	Device for filtering, concentrating and recovering helminthe eggs, larvae, protozoa and juvenile nematodes from fixed/preserved feces.	same
Specimen type	Fecal specimens	same
Technology	Filtration, reagent separation and concentration via centrifugation	same
Level of skill	Moderately complex	same
<b>Differences</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Procedure	8ml Proto-fix CLR	10% formalin
Procedure	4 ml ethyl acetate	5 ml ethyl acetate

**K. Standard/Guidance Document referenced (if applicable):**

Not applicable

**L. Test Principle:**

Para-Pro™ fc50 is a large surface-area filtration device utilizing a 1.6 mm<sup>2</sup> opening in a cone shape to maximize the filtration area. When a fixed/preserved specimen is filtered, by gravity, through the filter device, the larger fecal debris is separated from the preserved fecal specimen. This device traps the fecal debris allowing large parasite forms to pass through the device into a collection centrifuge tube. The device is designed to accommodate a standard 30ml vial containing a suitable fixative for intestinal parasitic concentration procedures (10% buffered formalin; SAF sodium

acetate acetic acid formaldehyde; and Proto-fix™ CLR), creating a completely closed system. On the opposite end the device is attached to a collection tube consisting of a 50ml centrifuge tube and inverted to initiate the gravity filtration process. The air transfer between the 30 ml collection vial and the receiver centrifuge tube is accomplished through the opening at the top of the cone. The filtered specimen, collected in the centrifuge tube, can be concentrated by the formalin ethyl acetate method or the CONSED method, resulting in a pellet or sediment that contains the parasitic material, if present in the sample, and viewed microscopically on an appropriate cover-slipped glass slide using standard wet mount procedures.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

a. *Precision/Reproducibility:*

Not applicable for this type device. Recovery studies were performed.

The samples were tested with a conventional analytical method, formalin/ethyl-acetate concentration procedure, using human fecal samples. Each specimen recovered duplicate types of parasitic stages, showing only a slight difference in the recovered parasitic load within each specimen. The parasitic load, per 50 uL aliquot of the concentrated pellet, resulted in 1,849 ova and parasites for the test device when samples were fixed and tested using 10% formalin and 1,211 ova and parasites for the Predicate device when tested using duplicate samples fixed in 10% formalin. This represents 34.3% more parasitic forms recovered in the test device as compared to the Predicate device.

b. *Linearity/assay reportable range:*

Not applicable

c. *Traceability (controls, calibrators, or method):*

Not applicable

d. *Detection limit:*

Not applicable

e. *Analytical specificity:*

Not applicable

f. *Assay cut-off*

Not applicable

2. Comparison studies:

a. *Method comparison with gold standard:*

The data for SAF fixative samples showed an increase of 287 parasitic stages for the test device, when compared to the Predicate device. There was a (28% increase in parasitic stages). The data for Proto-fix CLR showed an increase of 1,043 parasitic stages for the test device when compared to the predicate device. (39% increase in parasitic stages)

3. Clinical studies:

a. *Clinical sensitivity:*

*b. Clinical specificity:*

Refer to (a.) above

*c. Other clinical supportive data (when a and b is not applicable):*

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range: (Interpretive Criteria)

Not applicable

**N. Conclusion:**

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