

K970225

Section II: 510(k) Summary of Safety and Effectiveness

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Submitter: Alpha Therapeutic Corporation
5555 Valley Boulevard
Los Angeles, California 90032

Establishment Registration Number: 2022872

Contact Person: M. Sue Preston
Phone Number: (213) 225-2221
Facsimile Number: (213) 227-7613

Device Name:

Proprietary Name: Alpha Micron®-20/40 Microaggregate Filter

Common / Usual Name: Microaggregate Filter

Product Code: 80 CAK (Microfilter, Blood Transfusion)

Classification Name: Intravascular Administration Set
(21 CFR § 880.5440)

Classification: Class II (performance standards)

Devices for Which Substantial Equivalence is Claimed:

1. Alpha Micron®-20 Microaggregate Filter, 510(k) Number K955515
2. Alpha Micron®-40 Microaggregate Filter, 510(k) Number K810761A

Device Description:

The Alpha Micron®-20/40 Microaggregate Filter is a filter used for the filtration of microaggregate debris from plasma derivative products in order to aid in the prevention of pulmonary embolization. The device is designed to be utilized in either of two applications; by syringe, or by administration set. The syringe is inserted into the exposed inlet of the filter while the spike end is inserted into the bottle (or bag) of the plasma derivative. The blood plasma derivative is aspirated through the filter into the syringe resulting in

filtration. The administration set is placed into the exposed inlet of the filter while the spike end is attached to an infusion set. The plasma derivative is drawn through the filter during administration resulting in filtration.

Intended Use of the Device:

The intended use of the Alpha Micron®-20/40 Microaggregate Filter is for filtering microaggregate debris from plasma derivative products to prevent pulmonary embolization.

Substantial Equivalence:

The Alpha Micron®-20/40 Microaggregate Filter is substantially equivalent to several other legally marketed devices in the United States. Two such devices are currently legally marketed by Alpha Therapeutic Corporation. The Alpha Micron®-20/40 Microaggregate Filter functions in a manner identical to, and is intended for the same use as, both the Alpha Micron®-20 Microaggregate Filter and the Alpha Micron®-40 Microaggregate Filter. Both of these devices are currently manufactured by Alpha Therapeutic Corporation.