SECTION 5

510(K) SUMMARY

5. 510(K) SUMMARY

The following 510(k) Summary is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

510(K) SUMMARY

5.1 Submitter Information

A. Company Name:	Suneva Medical, Inc.
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C. Company Phone:	(858) 550-9999
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E. Contact Person:	Pamela Misajon Chief Compliance Officer and VP, Regulatory & Quality Affairs pmisajon@sumenvamedical.com
F. Date:	August 27, 2020

5.2 Device Identification

A. Device Trade Name:	Amplifine Gel Separator Tube
B. Common Name:	Platelet Rich Plasma Preparation System
C. Classification Name(s):	Automated blood cell separator
D. Classification Regulation(s):	21 CFR 864.9245
E. Device Class:	Class II
F. Product Code(s):	ORG
G. Advisory Panel:	Hematology

5.3 Identification of Predicate Devices

The Amplifine Gel Separator Tube System is substantially equivalent to the following device, which is cleared for commercial distribution in the United States:

- Healeon HD PRP manufactured by Healeon Medical, Inc. and cleared for commercial distribution under 510(k) BK170136

No reference devices were used in this submission.

5.4 Device Description

The Amplifine Gel Separator Tube is a blood collection tube, provided in a blister tray used for Platelet Rich Plasma (PRP) preparation from peripheral blood. The product contains

ACD-A anti-coagulant. Centrifugation of the tube blood collector separates the blood components by density; the system separates and concentrates the platelets into the plasma (platelet rich plasma or PRP) from an autologous blood drawn at the time of treatment.

The Amplifine Gel Separator Tube is an external communication device for a limited contact duration (≤ 24 hours). The Suneva HD PRP is provided "STERILE" by Gamma irradiation and is labeled "Non-pyrogenic" and for "Single-Use".

5.5 Indications for Use

The Amplifine Gel Separator Tube is designed to be used for the safe and rapid preparation of autologous platelet-rich-plasma (PRP) from a small sample of peripheral blood at the patient point of care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.

5.6 Technological Characteristics

The fundamental scientific technology, materials, processing method and mechanics of operation of the Amplifine Gel Separator Tube is similar to the predicate device. Both devices are single-use, sterile systems, designed to concentrate and aid in the separation of a starting source material (blood) by density through centrifugation to obtain Platelet Rich Plasma (PRP).

5.7 Summary of Testing Performed

A program of design verification testing was conducted to demonstrate that the product performance characteristics of the Amplifine Gel Separator Tube is equivalent to the predicate device, and biocompatibility testing was conducted to demonstrate the biological safety.

Test results indicate that the device is substantially equivalent to the predicate device and satisfies mechanical performance requirements for its intended use. Biocompatibility testing demonstrated the safety of the Amplifine Gel Separator Tube.

Prospective testing conducted for the Amplifine Gel Separator Tube are shown in **Table 5.1** below:

TABLE 5.1: PROSPECTIVE TESTING OF AMPLIFINE GEL SEPARATOR TUBE

Type	Testing
Product Performance	• Platelet Concentration Factor • Platelet Yield • pH of platelet concentrate • Platelet Activation • Platelet Aggregation • Hypotonic Stress Response • Hematology parameters • Bone Graft Retention • Product Gamma sterilization • Shipping and Packaging testing • Stability testing
Biocompatibility	• Chemical Characterization – Extractables • Cytotoxicity • Sensitization • Intracutaneous Reactivity • Acute Systemic Toxicity • In Vitro Hemolytic • ASTM Hemolysis • Pyrogenicity • Biological and Toxicological Risk Assessment

5.8 Conclusions Drawn from Studies

The results of testing demonstrate that the Amplifine Gel Separator Tube is substantially equivalent to the predicate device regarding design, function, technological characteristics, and indications for use.