# 510(K) SUMMARY

## 1. Submitter Information

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|---|---|
| A. Company Name: | Forever labs, Inc. |
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## 2. Device Identification

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|---|---|
| A. Device Trade Name: | PlateletQuick PRP |
| 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 |

## 3. Identification of Predicate Devices

The PlateletQuick PRP is substantially equivalent to the following device, which is cleared for commercial distribution in the United States:

- Suneva Amplifine HD PRP manufactured by Suneva Medical, Inc. and cleared for commercial distribution under 510(k) BK200477.

No reference devices were used in this submission.

## 4. Device Description

The PlateletQuick PRP is composed of:

1) Amplifine HD PRP tube (blood collection tube) with ACD-A in a blister tray,

2) Centrifugation solution contained in a Sterile Clear Borosilicate Glass vial with a Butyl Rubber cap, and

3) Amplifine HD PRP tube 15ml (blood collection tube) in a blister tray, without ACD-A or separator gel.

The PlateletQuick PRP is used for Platelet Rich Plasma (PRP) preparation from peripheral blood. Centrifugation of the blood collection tube and the subsequent centrifugation of the PRP with centrifugation solution 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 PlateletQuick PRP is an external communicating device for a limited contact duration (≤24 hours). The PlateletQuick PRP is provided "STERILE"; 1) the blood collection tube is sterilized by Gamma irradiation and the 2) centrifugation solution vial is sterilized by moist heat. Its labeled as "Single-Use".

## 5. Indications for Use

The PlateletQuick PRP 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.

## 6. Technological Characteristics

The fundamental scientific technology, materials, processing method and mechanics of operation of the PlateletQuick PRP 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). Table 1 outlines a detailed comparison between the subject and predicate devices.

**Table 1: PlateletQuick PRP – Predicate Device Comparisons**

| Comparison Feature | PlateletQuick PRP – Subject Device | Suneva Amplifine HD PRP – Predicate Device BK200477 | Comparison results |
|---|---|---|---|
| Indications for Use | 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 | 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 | Same |
| Components | • Tube; Polyethylene Terephthalate (PET)<br>• Tube cap; (medical brominated butyl rubber)<br>• ACD-A; (citric acid, sodium citrate and dextrose)<br>• Separation Gel; (serum separating gel TGHM)<br>• Sterile Vial (Clear Borosilicate Glass vial with a Butyl Rubber)<br>• Centrifugation solution - Poly (ethylene glycol) 6000 (PEG) & Dextran 500 (Dex) | • Tube; Polyethylene Terephthalate (PET)<br>• Tube cap; (medical brominated butyl rubber)<br>• ACD-A; (citric acid, sodium citrate and dextrose)<br>• Separation Gel; (serum separating gel TGHM) | Same components; PlateletQuick PRP adds two (2) more components that are added in the second centrifugation step. Biocompatibility testing was performed to address the added two components; no substantial difference was identified per the product performance requirements between the Proposed and Predicate Device. |
| Biocompatibility Testing (ISO 10993-1) | Yes | Yes | Same results. |

| Comparison Feature | PlateletQuick PRP – Subject Device | Suneva Amplifine HD PRP – Predicate Device BK200477 | Comparison results |
|---|---|---|---|
| Packaging | Tube: Thermoformed Blister seal with Tyvek® Lid<br>Centrifugation solution in a Sterile Clear Borosilicate Glass vial with a Butyl Rubber | Thermoformed Blister seal with Tyvek® Lid | Same for the tube.<br>A second step process was added that required an additional sterile container (Centrifugation solution in a Sterile vial). |
| Provided Sterile? | Yes<br>Tube: (Gamma)<br>Vial: (moist-heat) | Yes (Gamma) | Same for the tube.<br>Added the sterile vial per moist-heat. |
| Nonpyrogenic? | Yes | Yes | Same |
| Single-Use | Yes | Yes | Same |
| PRP separation process | Centrifugation process, a 2-spin sequence | Centrifugation process, only one spin sequence | Similar, first and second spin are centrifugation processes that separate the PRP from the other blood components |
| Centrifugation solution | Centrifugation solution mix with portion of extracted PRP before 2-spin process | Not part of the process | Added process step to support the PRP extraction; this process was part of the product performance testing ensuring similar PRP extraction as predicate device. |

## 7. Summary of Testing Performed

A program of design verification testing was conducted to demonstrate that the product performance characteristics of the PlateletQuick PRP is substantially 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 devices and satisfies mechanical performance requirements for its intended use. Biocompatibility testing demonstrated the safety of the PlateletQuick PRP.

Prospective testing conducted for the PlateletQuick PRP are shown in Table 2 below:

**Table 2: Prospective Testing of PlateletQuick PRP**

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

## 8. Conclusions Drawn from Studies

The results of testing demonstrate that the PlateletQuick PRP System is substantially equivalent to the predicate device regarding design, function, technological characteristics, and indications for use.