510(k) Summary

I.	**Company**	Gale Force Aesthetics, LLC 1644 Ramona Way Alamo, CA 94507
II.	**Contact**	Jayson Jonsson CEO Phone: (b) (6) Email: jjonsson@galeforcellc.com
III.	**Product Trade Name**	Illuminate PRP
IV.	**Common Name**	Platelet and Plasma Separator for Bone Graft Handling
V.	**Classification Name**	Automated blood cell separator
VI.	**Regulation Number**	21 CFR 864.9245
VII.	**Device Class**	Class II
VIII.	**Classification Product Code**	ORG
IX.	**Predicate Device**	BK110035 Tropocells by Estar Technologies

X. **Description**

The Illuminate PRP Platelet Preparation System consists of an evacuated tube intended for the collection of whole blood and the separation of platelet rich plasma. The plasma separation medium is comprised of a thixotropic separator gel which has specific gravity. This configuration permits plasma separation during a single centrifugation step. The separated sample can be transported without being removed from the tube since the gel forms a stable barrier between the plasma layers. The PRP tube is a sterile, single use, media containing vacuum evacuated tube that is intended for separating and concentrating blood components along with the use of a desktop centrifuge.

The gel separation technology is based on the principle of density gradient centrifugation. The blood components differ from each other based on their respective densities. When the blood is added into the tube and centrifuged, the components separate out based on their densities.

The centrifuge and blood draw accessories are not included with the system and is not a part of the present submission.

XI. **Indications for Use**

Illuminate PRP is indicated 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.

XII. **Summary of the Technological Characteristics**

Evacuated tube containing a plasma separation medium comprised of a thixotropic separator gel which has specific gravity of (b) (4) . The gel separation technology is based on the principle of density gradient centrifugation. The blood components differ from each other based on their respective densities. When the blood is added into the tube and centrifuged, the components separate out based on their densities.

The fundamental scientific technology, materials of construction, processing methods and mechanism of operation of the subject device are substantially equivalent to the predicate device. All devices are provided as sterile concentrating systems, designed to concentrate and aid in separation of a starting source material (blood) by density using a centrifuge. All devices include a single-use, disposable receptacle (e.g. concentrating device, separator, centrifuge tube assembly, etc.) that is designed to accept a volume of blood, and then undergo centrifugal processing in order to obtain platelet rich plasma (PRP). The table below summarizes the comparison of characteristics between the subject and predicate devices.

Description	**Illuminate™ PRP (Subject Device)**	**TropoCells (Predicate Device)**
510(K)	**BK241042**	**BK110035**
Product code	ORG	ORG
Manufacturer	DiponEd BioIntelligence LLP	Estar Technologies Ltd
Indications for Use statement	The Illuminate PRP Kit 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's point of care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling Characteristics.	The TropoCells PRP Kit 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's point of care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling Characteristics.
Prescription/Healthcare professional/OTC	Prescription	Prescription
System components	The Illuminate PRP kit contains an evacuated glass tube, thixotropic separator gel, sodium citrate as anticoagulant	Blood collection system, Vacuum tube for PRP separation with GEL & MNC7 anticoagulant
Materials	Medical grade polymers and elastomers, separator gel (thixotropic) and sodium citrate as anticoagulant	Medical grade polymers, elastomers and anticoagulant
Principle of Operation	Separation of blood based on density	Separation of blood based on density
Method of processing	Centrifugation	Centrifugation
Centrifuge device	General purpose centrifuge	General purpose centrifuge
Sterile	Sterile, Gamma	Sterile, Gamma
Sizes	22mL	11mL and 22mL

XIII. **Discussion of the Non-Clinical Testing**

Biocompatibility Testing
Biocompatibility testing on the patient contacting materials of the device was conducted in accordance with ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process. Per ISO 10993-1, Illuminate PRP is categorized as an externally communicating device, with limited exposure (contact < 24 hours) with indirect blood contact. Testing included cytotoxicity (per ISO 10993-5), sensitization & intracutaneous reactivity (per ISO 10993-10), acute systemic toxicity (per ISO 10993-11), pyrogenicity per USP: 151 and USP 41-NF 36.

Sterilization Validation
A sterilization qualification using the (b) (4) method in compliance with ISO 11137 was performed to validate a gamma sterilization process for the Illuminate PRP Tubes. Results demonstrated that the product is reliably sterilized to a 10^{-6} sterility assurance level (SAL) using predetermined parameters. Gale Force intends to use this same procedure to increase sterilization efficiency, such as load capacity, configuration, or location post clearance.

Transport and Shelf-life
A transportation validation per ASTM D4169 and a packaging shelf life validation per ISO 11607 was conducted using accelerated aging to demonstrate that the package is designed, manufactured, and packed in such a way that the characteristics and performances of the packaging during the intended use will not adversely be affected during the full life cycle of the device; that there is assurance that the device is sterile when placed in the market and will remain sterile, under the storage and transport conditions laid down, until the protective packaging is opened; and that the product will be kept without deterioration at the high level of cleanliness so as to minimize the risk of microbial contamination.

Predicate Equivalency Evaluation
A study was conducted to compare platelet concentrates produced by the Illuminate PRP and those produced by the predicate. Parameters included platelet yields, platelet recoveries, average PRP platelet concentration, pH, p-selectin expression on resting platelets, platelet response to ADP-stimulation, platelet function, platelet aggregation, hypotonic stress response, and Bone graft material retention. This evaluation demonstrated that the platelet concentrates obtained by Illuminate PRP is substantially equivalent to those of the predicate.

Additionally, Illuminate PRP and the predicate possess the same indications, device class, device code, principles of operation, methods of processing, sterility assurance level, and biocompatibility. The subject device uses components readily available to the user, and the size, where the larger size of the subject device provides increased usability. None of the differences negatively impact the device's substantial equivalence when compared to the predicate. All validations, verifications, and qualifications passed the predetermined acceptance criteria. The Illuminate PRP therefore has been shown to be substantially equivalent to the predicate.