

# US FDA 510(k) Clearance

## RegenKit<sup>®</sup>-BCT

**Device Name:**

RegenKit<sup>®</sup>-BCT Family Kits

**Models:**

RK-BCT-1

RK-BCT-2

RK-BCT-3

RK-BCT-4

**FDA Clearance:**

BK110061

**Indication for Use:**

The RegenKit<sup>®</sup>-BCT Family Kit is designed to be used for the safe and rapid preparation of autologous platelet rich plasma (PRP) from a small sample of 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 RegenKit<sup>®</sup>-BCT Family Kits are for single use only.



# US FDA 510(k) Clearance

## RegenKit®-BCT Plus

**Device Name:**

RegenKit®-BCT Plus Family Kits

**Models:**

RK-BCT-1 Plus

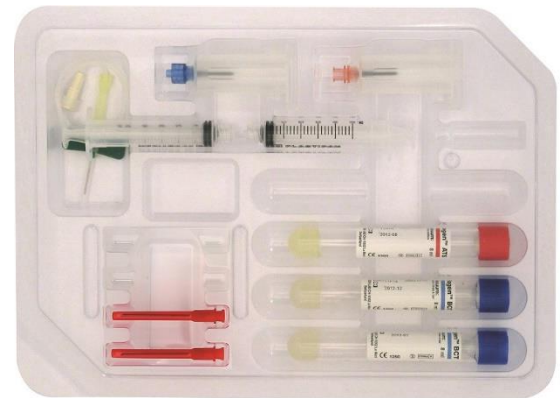
RK-BCT-2 Plus

**FDA Clearance:**

BK120066

**Indication for Use:**

The RegenKit®-BCT Plus Family Kits are designed to be used for the safe and rapid preparation of autologous platelet rich plasma (PRP) and autologous serum from a small sample of blood at the patient's point of care. The combined PRP and autologous serum are mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics. The RegenKit®-BCT Plus Family Kits are for single use only.



# US FDA 510(k) Clearance

## RegenKit<sup>®</sup>-THT

**Device Name:**  
RegenKit<sup>®</sup>-THT

**FDA Clearance:**  
BK090048

**Indication for Use:**

The RegenKit<sup>®</sup>-THT is designed to be used for the safe and rapid preparation of autologous platelet rich plasma (PRP) from a small sample of blood at the patient's point of care. The PRP is mixed with autograft and/or allograft bone prior to application to an orthopaedic surgical site as deemed necessary by the clinical use requirements. The RegenKit<sup>®</sup>-THT is for single use only.



# US FDA 510(k) Clearance

## Regen Spray Applicator

**Device Name:**

Regen Spray Applicator

**Models:**

R-A/NAC1

R-A/NAC3

**FDA Clearance:**

K122122

**Indication for Use:**

Regen Spray Applicator is designed for use in applying two non-homogeneous fluids or liquids to a treatment site as deemed necessary by the clinical use requirements.

Regen Spray Applicator is for single use only.

