ViviGen™ Cellular Bone Matrix

The right cells. The right time.

When is a 510(k) Required?

A **510(k)** is a pre-market submission made to the Food and Drug Administration (FDA) to demonstrate that a medical device is as safe and effective, that is, substantially equivalent, to a legally marketed device. Once the device is determined to be substantially equivalent, it can then be marketed in the U.S.

LifeNet Health products are considered medical devices when the FDA determines that they have been more than minimally processed. To be considered beyond minimally processed, an original characteristic of a structural tissue must be altered and that characteristic has to be relevant in that it has a potential effect on the utility of the tissue for reconstruction, repair or replacement.

Articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient, and are considered minimally manipulated are called **H**uman **C**ellular and **T**issue-based **P**roducts **(HCT/P)**. HCT/P's must also be intended for homologous use and cannot be combined with another article (except for water, crystalloids, or a sterilizing, preserving, or storage agent). The product must either have no systemic effect and cannot be dependent upon the metabolic activity of living cells for the primary function; or it may have a systemic effect or depend upon the metabolic activity of the other cells for the primary function, as long as it is for autologous use, allogeneic use in a first or second-degree relative, or reproductive use.

Manufacturers of HCT/P's, such as LifeNet Health, are required by the FDA to comply with Current Good Tissue Practices (CGTP). This includes proper handling, processing, labeling, and record-keeping procedures. Under these regulations, LifeNet Health must screen and test all donors for risk factors, and clinical evidence of relevant communicable disease agents.

PRODUCT	HCT/P	510(K)
ViviGen™ - Cellular Bone Matrix	✓	
VertiGRAFT®	✓	
I/C Graft Chamber®		✓

LifeNet Health®

Saving Lives. Restoring Health. Giving Hope.

68-30-032-02 .00
DSUS/SPN/0115/0726 01/15