

Product(s):

NMP Products include the following brand names and formats:

NMP[®] Cancellous, NMP[®] Fibers, NMP[®] Micro Particulates, NMP[®] FiberMatrix, NMP[®] FiberMatrixC, NMP[®] Strips, InduceXT[®], Induce Oi-9[™] FiberMatrix, Induce Oi-9[™] Micro Particulates and Induce Oi-9[™] Cancellous.

NMP products consist of particles and/or fibers derived from human cortical, cancellous or cortico-cancellous bone, as well as strips derived from blocks of trabecular bone (NMP Strips).

Intended Use:

NMP products are all intended for use as a bone void filler for filling voids and gaps in the skeletal system that are not intrinsic to the stability of the bony structure.

Source and Tissue Recovery:

We have partnered with tissue banks accredited by the Association for Advancing Tissue and Biologics (AATB) and these tissue banks perform donor screening and tissue procurement procedures. The tissue donor eligibility criteria comply with the FDA regulations 21 CFR Part §1271. All procedures for donor screening, infectious disease and microbiologic testing meet the current AATB Standards.

Manufacturer:

We have partnered with AATB Accredited tissue banks to process human bone using our proprietary NMP process to prepare NMP products. All tissue processing and manufacturing procedures follow FDA's current Good Tissue Practice (cGTP) and meet the requirements of 21 CFR Part 1271 and AATB Standards for Tissue Banking.

Product Preparation and Use

At time of use, the NMP Product packaging is opened in the operating room and it is recommended that the NMP allograft tissue be rehydrated with blood, sterile saline (0.9%), or other sterile isotonic solution (as determined and provided by the clinician). Each product package contains an Instructions for Use (IFU) that should be reviewed for specific product information.

NMP Products Meet the Criteria for Regulation as “361” Products

Induce Biologic’s NMP products are tissue-based products that meet the criteria for regulation solely under section 361 of FDA’s Public Health Service (PHS) Act and 21 CFR part 1271. NMP products contain human bone intended for implantation into human recipients. They meet the definition of human cells, tissues and cellular and tissue-based products (HCT/Ps) per 21 CFR 1271.3(d)¹. Additionally, an HCT/P must satisfy all four criteria at 21 CFR 1271.10(a)² to be regulated solely under section 361 of PHS Act and considered 361 HCT/Ps. NMP products are processed in a manner that meets all four criteria including minimally manipulated, intended for homologous use, do not have a systemic effect, and not combined with another article, to be considered 361 HCT/Ps.

No Clearance or Premarket Approval is Required for “361” HCT/P Products

As Induce Biologic’s NMP products meet the criteria for regulation as a 361 HCT/Ps (as defined above), they do not require a 510(k) clearance or premarket review and approval.

Conclusion

NMP products meet criteria for regulation solely under section 361 of FDA PHS Act and 21 CFR Part 1271 “as bone void fillers for filling voids and gaps in the skeletal system that are not intrinsic to the stability of the bony structure.”

Induce Biologic’s NMP products do not contain stem cells and do not require clearance or premarket approval from the FDA. All tissue processing and manufacturing procedures are performed by AATB Accredited tissue banks and are produced in compliance with FDA’s current Good Tissue Practice (cGTP) and the requirements in 21 CFR Part 1271.

¹ [21 CFR 1271.3\(d\)](#) defines HCT/Ps as “Human cells, tissues, or cellular or tissue-based products (HCT/Ps) means articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. Examples of HCT/Ps include, but are not limited to, bone, ligament, skin, dura mater, heart valve, cornea, hematopoietic stem/progenitor cells derived from peripheral and cord blood, manipulated autologous chondrocytes, epithelial cells on a synthetic matrix, and semen or other reproductive tissue.”

² The four criteria can be found at [21 CFR 1271.10\(a\)](#).

³ FDA guidance document: [Regulatory Considerations for Human Cell, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use Guidance for Industry and Food and Drug Administration Staff](#)

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