Regulatory Summary of

Natural Matrix Proteins (NMP™) Products
Induce Biologics USA Inc.

Product(s):
NMP Particulates, NMP Fibers, and NMP Cancellous Strips - NMP products consists of particles (NMP Particulates), fibers (NMP Fibers) derived from human cortical, cancellous or cortico-cancellous bone, as well as strips derived from blocks of trabecular bone (NMP Cancellous 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 American Association of Tissue Banks (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 Particulates, NMP Fibers, and NMP Cancellous Strips. 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 Particulates, NMP Fibers, and NMP Cancellous Strips 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 demineralized 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.

FDA's Tissue Reference Group reviewed the Request for Recommendation for NMP Particulates, NMP Fibers, and NMP Cancellous strips, and concluded that these products "appear to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR 1271."

No Clearance or Premarket Approval is Required for "361" HCT/P Products
Induce Biologic's NMP products do not contain stem cells and since they are considered 361 HCT/Ps, they do not require a 510(k) clearance or premarket review and approval.

Conclusion
With recommendation by the FDA's Tissue Reference Group, Induce Biologics USA Inc. has ascertained its NMP products (NMP Particulates, NMP Fibers, and NMP Cancellous Strips) meet the 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."

As 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 (July 2020).