Ostiio: A Smart, Fully-Implantable CMF Distractor

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> *"Unlike typical grants, ITP enables productization, allowing us to bring our life-altering tech a step closer to reality."*

https://ostiio.com

Clinical Need

Each year >200K newborns suffer from conditions that restrict growth of the skull or jawbone. Left untreated these can have life threatening outcomes in an otherwise healthy child. However, treatments are complex and traumatic. Distraction is a gentler therapy that uses a device to slowly expand abnormal bone, but: 1) distractors are semi-buried, increasing complication risk; 2) manual expansion is performed by parents, leading to noncompliance; 3) surgeons are blinded to treatment, forcing weekly x-rays & exams.

Solution

Ostiio's integrated therapy uniquely solves pain points of distraction to improve patient outcomes and experience while reducing cost. 1) The fully buried implant is magnetically expanded without contact, removing the complication risk of semi-buried devices. 2) The automated driver simplifies expansion to a button push, reducing parental noncompliance. 3) The remote monitoring platform allows surgeons to track treatment progress and address complications early on, reducing post-op follow-up.

Competitive Advantage

Although distraction is the segment within the craniomaxillofacial device market that offers differentiation opportunity, major competitors have been focused on iterating upon the same basic technology that was first introduced to market >20 years ago to provide greater flexibility to the surgeon in the operating room. But treatment takes place at home. Ostiio instead is focused on transforming how distraction is provided by parents and monitored by surgeons to improve patient outcomes and experience while reducing cost.

ITP Support

The ITP program has enabled Ostiio to advance its integrated therapy from the early prototyping phase into a formal, staged product development process. Working within a quality management system, Ostiio has developed functional, working prototypes that exceed the most critical product specification by more than 2.5 times. In parallel, Ostiio has been able to initiate key regulatory activities and complete important market validation work.

Clinical Translation Pathway

Publications: Zhang et al. Evaluation of parental and surgeon stressors and perceptions of distraction osteogenesis in pediatric craniofacial patients: a cross-sectional survey study. Childs Nerv Syst 2018

Zapatero et al. A quantification of scalp thickness pre- and post-posterior vault distraction osteogenesis. Plast Reconstr Surg (manuscript accepted)

IP: PCT/US2018/021269 Systems and Methods for Contactless Craniomaxillofacial Distraction

PCT/US2020/017918 Systems and Methods for a Smart, Implantable Craniomaxillofacial Distractor

Anticipated regulatory pathway: Class II medical device via 510(k) pathway

Anticipated commercialization strategy: Pilot therapy in influential centers and leverage these KOL relationships to drive awareness

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