510(k) Summary
(K182287)

This summary of 510(K) is being submitted in accordance with requirements of 21 CFR Part 807.92.

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1. **Applicant / Submitter**

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3. **Device**

- Trade Name: MEDINAUT Plus
- Common Name: Inflatable Bone Tamp
- Classification Name: Arthroscope
  Tamp
  Polymethylmethacrylate (PMMA) bone cement
- Product Code: HRX, HXG, NDN
- Classification regulation: Class II, 21 CFR 888.1100/ 888.4540/ 888.3027

4. **Predicate Device:**

- Kyphon Express II by Medtronic Sofamor Danek (K123771)

5. Description:

The MEDINAUT Plus Kyphoplasty System is designed to reduce compression fracture and create a void in cancellous bone in the spine. By creating a space in the operating point, the major benefits of MEDINAUT Plus Kyphoplasty System are the reduction in pain and the increase of patient`s functional abilities, which allow for the patient's return to the previous level of activity.
The MEDINAUT Plus Kyphoplasty System consists of the Balloon Expander, Balloon Catheter, Cement Dispenser System, Cement Mixer System and Syringe.

The Balloon Catheter consists of an inner-outer tube, Y-port and an inflatable balloon located at the distal tip. The radiopaque markers located at the distal and proximal end allow fluoroscopic visualization of the deflated balloon catheter during positioning.
The Balloon Expander consists of a gauge, housing, a half nut, a plunger, a piston, a hose, a luer connector and a 3 way valve. The Balloon Expander is used for inflating the balloon by rotating the plunger clockwise. The lock mechanism maintains pressure.
The Cement Dispenser System consists of Cannula, Needle (3 types: Bevel, Diamond, Trocar), Spacer, Biopsy, Biopsy Cap, Cement Filler, Cement Pusher and Cement Side Filler.
The Cement Mixer System consists of Cement Mixer, Tube, Cap, Funnel and Pusher. The user can mix cement inside the cylinder by moving the mixer up and down repeatedly and apply the cement into a patient by rotating the pusher handle.
The Syringe is an optional device. If there is air found in the Catheter Balloon before surgery, the user can remove the air with this syringe.
All the components including Balloon Expander, Balloon Catheter, Cement Dispenser System, Cement Mixer System and Syringe are supplied sterile and are disposable.

6. Indication for use:

MEDINAUT Plus Kyphoplasty System is intended to be used as a conventional bone tamp for the reduction of fractures and/or creation of a void in cancellous bone in the spine (including use during balloon kyphoplasty with a PMMA-based bone cement that is cleared for use in kyphoplasty procedures), hand, tibia, radius, and calcaneus.

7. Basis for Substantial Equivalence

MEDINAUT Plus is substantially equivalent to the Kyphon Express II (K123771) made by Medtronic Sofamor Danek. There are no significant differences between the subject devices and the predicate device. The subject devices have the same intended use as the identified predicate device and they are similar in fundamental scientific technology, design, and size.
The materials used in the subject devices might be different from the predicate device; however, the biocompatibility testing results of the subject device support that the subject

devices are biocompatible and the performance testing results show that the subject device would perform as well as the predicate device.

		Subject Device			Predicate Device		
Device Name		**MEDINAUT Plus**			**Kyphon Express II**		
510(k) Number		K182287			K123771		
Product Code		HRX, HXG, NDN			HRX, HXG, NDN		
Common Name		Inflatable Bone Tamp			Inflatable Bone Tamp		
Manufacturer		IMEDICOM Co., Ltd.			Medtronic Sofamor Danek		
Indications for Use		MEDINAUT Plus Kyphoplasty System is intended to be used as a conventional bone tamp for the reduction of fractures and/or creation of a void in cancellous bone in the spine (including use during balloon kyphoplasty with a PMMA-based bone cement that is cleared for use in kyphoplasty procedures), hand, tibia, radius, and calcaneus.			The KYPHON Xpander II Inflatable Bone Tamps and Kyphon Express II Inflatable Bone Tamps are intended to be used as a conventional bone tamp for the reduction of fractures and/or creation of a void in cancellous bone in the spine (including use during balloon kyphoplasty with a PMMA-based bone cement that is cleared for use in kyphoplasty procedures), hand, tibia, radius, and calcaneus.		
Balloon Size		10, 15, 20mm			10, 15, 20mm		
Balloon Specification	**Model #**	PIBE-10	PIBE-15	PIBE-20	KE102	KE152	KE202
	Length of Balloon	10.0mm	15.0mm	20.0mm	10.0mm	15.0mm	20.0mm
	Max. inflation volume	3cc	4cc	5cc	3cc	4cc	5cc
	Max. inflated dimension	15.0mm	15.3mm	16.0mm	15.0mm	15.3mm	16.0mm
	Max. inflated length	18.7mm	24.4mm	28.5mm	18.7mm	24.4mm	28.5mm
Bone Tamp Max. Inflation pressure		700 psi			700 psi		
Packaging		Pouch, Tyvek Blister Tray, Cardboard Box			Pouch, Tyvek Blister Tray, Cardboard Box		
Biocompatibility		Meets ISO 10993			Meets ISO 10993		

8. Non-Clinical Testing

- Sterilization validating testing has been performed in accordance with ISO 11137-1, 2, 3 and ISO 11737-1, 2, 3, and the test results met the pre-set criteria.
- The tests to validate the shelf life of the device were conducted and the test results validated 3 year shelf life. Both the accelerated aging method in accordance to ASTM F1980 *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices* and the real time test were performed.
- Biocompatibility tests were performed in accordance with ISO 10993-4, 5, 7, 10, 11, and the test results supported that the subject devices are biocompatible.
- Various bench tests including Visual Inspection, Size Measurement, Liquid leakage under pressure, Tensile force, Burst strength, Balloon fatigue, Inflated balloon size, Balloon deflation, EO Gas residue, Sterility Test, Balloon rated burst pressure (RBP) in constrained condition, Balloon rated burst pressure (RBP) in unconstrained condition, Balloon Fatigue, Freedom from leakage and damage on inflation, Balloon diameter to inflation pressure, Insertion force and withdrawal force

The test results supported that the subject device is substantially equivalent to the predicate devices.

9. Conclusion

Based on the similarities, we conclude that the MEDINAUT Plus Kyphoplasty System is substantially equivalent to the predicate devices.