

510(K) SUMMARY

K962789

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is : K962789

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A. Submitter

Smith & Nephew Endoscopy
130 Forbes Boulevard
Mansfield, MA 02048

Establishment Registration Number: 1219602

B. Company Contact

Tedd Gosian
Clinical / Regulatory Manager

C. Device Name

Trade Name: MosaicPlasty® System
Common Name: Drill Bits, Chisels, Trephines, Tamps, Drill Guide
Classification Name: Orthopedic Manual Surgical Instruments, Template

D. Predicate/Legally Marketed Devices

All of the components in the MosaicPlasty System are Class I Exempt Devices, except drill bits and adapters which are Class I.

Predicate/Legally Marketed Devices include:

Drill Guide	Synthes®
Drill Bits	Synthes®
Gouges	Synthes®
Trephine Drills	Smith & Nephew Endoscopy
Tamps	Zimmer®
Bone Grafter	Instrument Makar®
Bone Compression Forceps	KMedic®

E. Device Description

The MosaicPlasty System is a kit composed of several orthopedic manual surgical instruments. These instruments include a drill guide, drill guide plugs, drill bits, tubular chisels, trephines, tamps, transfer tubes, bone block compressor, drill bit adapters and a sterilizing tray. All instruments are composed of stainless steel. The instruments range in diameter from 2.7 mm to 4.5 mm.

F. Intended Use

The components of the MosaicPlasty System are intended to be used for drilling bone, harvesting osteochondral bone grafts and transferring grafts to the drilled site.

G. Substantial Equivalence

The components of the MosaicPlasty System are Class I exempt devices, except drill bits and adapters which are Class I. The components are similar in design, function, materials and intended use as other devices currently in commercial distribution. All devices are composed of stainless steel. The intended use and commercially available devices are presented in the table below.

Risks to health have been addressed through the specified materials, processing controls, quality assurance, and compliance to the Medical Device Good Manufacturing Practices regulations.

Intended Use	Current Product MosaicPlasty Component	Substantially Equivalent Product
Drill Template	Drill Guide	Drill Guide (Synthes®)
Use with Template	Drill Plugs	Drill Sleeves (Synthes)
Drilling in Bone	Drill Bits	Drill Bits (Synthes)
Harvesting Bone Grafts	Tubular Chisels	Gouges (Synthes)
Cutting circular bone section	Trephines	Trephine Drills (Smith & Nephew Endoscopy)
Tamping Graft into site	Tamps	Tamps (Zimmer®)
Transferring bone graft to recipient site	Transfer Tubes	Bone Graftor (Instrument Makar®)
Adapting drill bit or trephine to orthopedic drill	Trephine Adapters (Quick Coupling, Power)	Quick Coupling Adapter (Synthes)
Compress bone block	Bone Plug Compressor	Bone Compression Forceps (KMedic®)

Applicant Fedell R. Dorian Date 8/9/86