

OMX Solutions Pty Ltd custom-made medical device, the OMX Craniofacial Fixation Plate, gains inclusion on the Australian Register of Therapeutic Goods.

February 25, 2020

OMX Solutions Pty Ltd is pleased to announce the Australian regulatory approval of its latest custom-made medical device (CMMDs), the OMX Craniofacial Fixation Plate Kit. A CMMD is a one-off medical device prescribed for the exclusive use of a particular patient and offers improved anatomical fit over conventional “off the shelf” medical devices.

The OMX Craniofacial Fixation Plate Kit is a CMMD designed to match the unique bone morphology of an individual patient. The intended use of the individually designed custom-made plate is for the fixation of fractures and osteotomies of both the maxilla and mandible. The system includes a custom-made, Titanium Ti-6Al-4V (Grade 5), fixation plate, fixation screws, a drill bit, driver blade and handle.

The inclusion of its custom-made Craniofacial Fixation Plate Kit in the Australian Register of Therapeutic Goods (ARTG) was recently published by the Australian Therapeutic Good Administration (TGA). The Australian Therapeutic Good Administration (TGA) regulates the supply and exportation of medical devices to ensure they meet required standards of quality, safety and performance. Therapeutic goods, such as the OMX Craniofacial Fixation Plate, entered in the Register (ARTG) can be lawfully supplied in Australia. The ARTG entry will also initiate Prosthesis List application or private insurer funding of the CMMD in the coming months.

About OMX Solutions Pty Ltd:

OMX Solutions Pty Ltd specialises in custom-made medical devices (CMMDs) for cranio-maxillofacial surgery applications. Since its establishment in 2016, the company embraced the 3D printing digital revolution and has a growing portfolio of medical implants including a custom TMJ joint replacement prosthesis, bespoke plating systems, bio-models, surgical splints and guides. Headquartered in Melbourne, OMX Solutions is an Australian owned company with a goal to be the world leader in the development of exciting new customized and personalized surgical products and devices that will become game-changers in Craniomaxillofacial surgery.

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