

ASX Announcement

3 July 2026

OncoSil Medical Files for FDA Approval of OncoSil™ Device

Key Highlights

- Documentation submitted to the U.S. Food and Drug Administration (FDA), completing the next step in the Humanitarian Device Exemption (HDE) application for the OncoSil™ device.
- Application now enters the FDA's review phase for commercial approval in the United States.
- If approved, the OncoSil™ device would become the first and only FDA-approved Class III medical device for the treatment of distal cholangiocarcinoma (dCCA).
- Approval would represent OncoSil Medical's first commercial regulatory approval in the United States and provide access to the world's largest medical device market.
- FDA review is expected to be completed within 45 days post submission of the documentation.

Sydney, Australia – 3 July 2026: OncoSil Medical Limited (ASX: OSL) ("OncoSil Medical" or "the Company"), a medical device company developing targeted radiation therapies for difficult-to-treat cancers, today announces it has completed the submission of its Humanitarian Device Exemption (HDE) application to the U.S. Food and Drug Administration (FDA) for the OncoSil™ device for the treatment of distal cholangiocarcinoma (dCCA).

Completion of the submission marks the next stage of the Company's HDE application process and places the application into the FDA's review phase.

Subject to FDA approval, the OncoSil™ device would become the first and only FDA-approved Class III medical device specifically indicated for the treatment of distal cholangiocarcinoma in the United States.

The FDA has advised the Company that it expects to complete its review within approximately 45 days and grant the HDE.

Approval under the HDE pathway would allow OncoSil Medical to commence commercialisation of the OncoSil™ device in the United States for this indication. It would also represent the Company's first regulatory approval in the U.S., a significant strategic milestone that would establish an important commercial platform for future growth.

Nigel Lange, CEO & Managing Director, said:

"This is one of the most important milestones in OncoSil Medical's journey to date. Completing our FDA submission reflects years of dedication from our team and our clinical partners and brings us to the final stage of the regulatory process in the United States."

For patients with distal cholangiocarcinoma, treatment options remain extremely limited. If approved, the OncoSil™ device has the potential to provide clinicians with a new localised treatment option for this challenging disease while establishing our first commercial presence in the U.S.

We recognise that the FDA review process remains ongoing and we look forward to working closely with the Agency as it completes its assessment. Reaching this stage is a testament to the quality of the clinical evidence, the strength of our regulatory strategy and the commitment of everyone who has contributed to the development of the OncoSil™ device."

The Humanitarian Device Exemption (HDE) pathway is designed to facilitate approval of medical devices intended to treat or diagnose diseases affecting fewer than 8,000 patients annually in the United States.

If approved, the HDE would authorise commercial marketing of the OncoSil™ device in the United States for the treatment of dCCA, subject to the regulatory requirements applicable to HDE-approved devices.

dCCA is a rare and aggressive form of bile duct cancer associated with poor prognosis and limited treatment options. Patients with untreated disease have a median survival measured in months, highlighting the significant unmet need for new treatment options.

Click [HERE](#) to view this announcement on Investor Hub.

Authorisation & Additional Information

This announcement was authorised by the Board of Directors of OncoSil Medical Limited.

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About OncoSil Medical

OncoSil Medical (ASX: OSL) is a global medical device company focused on Interventional Oncology. OncoSil Medical's mission is to improve the outcomes for people living with cancer by utilizing the selected and targeted intratumoural placement of Phosphorous-32 (³²P) Microparticles in addition to chemotherapy.

OncoSil Medical has developed OncoSil™ device for the treatment of unresectable locally advanced pancreatic cancer. Its targeted approach enables healthcare professionals to deliver a greater radiation dose directly into the tumour compared to external beam radiotherapy, while sparing surrounding critical organs.

Pancreatic cancer is the 12th most common cancer in men and the 11th most common cancer in women across the globe, with 500,000 new cases detected every year¹. Since pancreatic cancer is generally diagnosed at a later stage, it has a poor prognosis for long-term survival.

OncoSil™ has received CE Marking approval, providing marketing authorisation in both the EU and the UK. OncoSil™ is designated as a

breakthrough device in both Europe and the United States. It is currently approved for sale in 30+ countries including European Union, United Kingdom, Australia, Türkiye and Israel, with commercial treatments using the device already undertaken in Spain, Italy, Austria, Germany, Greece, Türkiye, Portugal, Israel and the UK.

To learn more, please visit: www.oncosil.com/

About HDE

Humanitarian Device Exemption (HDE) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

¹ <https://gco.iarc.fr/en>