

STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL

USAN (GH-140)	ILTAMIOCEL
PRONUNCIATION	il" ta mye' oh sel
THERAPEUTIC CLAIM	Augmentation or regeneration of muscle tissue through the use of muscle progenitor cells

DESCRIPTION

Cook MyoSite's autologous muscle derived cells (AMDC) are expanded (amplified) through a two-phase manufacturing process. The expansion is consistent with routine cell culture practices for adherent cells. During adherent cell culture expansion, cells replicate within a cell culture vessel until they reach an appropriate confluence (occupy an appropriate surface area within the vessel). Once the target confluence is reached, the cells are lifted off the culture flask with an enzyme which allows for the cells to be transferred into a larger culture flask, or multiple culture flasks, totaling a larger surface area for cell growth. The AMDC manufacturing process uses T-flasks, which are identified by their surface area: T25: 25 cm² surface area, T500: 500 cm² surface area.

TRADEMARK	None as yet
SPONSOR	Cook MyoSite, Inc.
CODE DESIGNATIONS	AMDC; AMDC-USR
UNII	QTA2A5N6BE
WHO NUMBER	11376

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