



RE: MicroCLAVE® Connector for use in Arterial Systems

Thank you for your interest in the MicroCLAVE by ICU Medical. The original CLAVE Connector has been accepted by the FDA for use in arterial systems according to FDA 510K#970855. The CLAVE and MicroCLAVE share essentially identical internal designs as they relate to the fluid path. The MicroCLAVE has slightly less deadspace, but the flow rate is equal and there are no fluid path restrictions in the MicroCLAVE. The MicroCLAVE is considered substantially equivalent to the standard CLAVE and therefore also appropriate for use in arterial systems. Both products are made up of three components; a non-compliant housing, non-complaint internal spike and a soft silicone seal. The mass and density of the silicone component will not interfere with pressure readings, or cause a dampening effect of the signal.

Thank you again for your interest, for further questions or concerns, please visit our website at www.icumed.com or contact our corporate offices at 800-824-7890 or 949-366-2183.

Sincerely,

A handwritten signature in black ink, appearing to read "Alison D Burcar", with a long horizontal flourish extending to the right.

Alison D Burcar
ICU Medical, Inc.