

K 960771

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**Summary of Safety and Effectiveness for the
RyMed Technologies SLAV™ Injection Ports**
submitted by
RyMed Technologies, Inc.
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Identification of a Legally Marketed Predicate Device

The RyMed Technologies SLAV™ Injection Port Systems are substantially equivalent Injection Ports Systems manufactured by:

- BRAUN MEDICAL, Bethlehem, Pennsylvania
- MEDEX, Hilliard, Ohio

Device Description

The RyMed Technologies SLAV™ Injection Port Systems are composed of either a Heparin Lock Injection Port, or a Y-Injection Site Port that contain a specialized two piece valve made from a medical grade clear plastic and a medical grade Silicone material. This specialized valve completely eliminates the use of Needles forcing compliance with the new OSHA standards of safety avoiding accidental needle stick injuries, the valve also provides excellent fluid Flow Rates, requires very low Priming Volumes, and it eliminates "dead spaces" that could entrap blood. This valve has the ability to activate injection ports a minimum of 100 times without leaking or change in its performance.

Intended for Use

The RyMed Technologies SLAV™ Injection Port Systems are intended for single patient use in intravenous and blood administration.

Summary of Technological Characteristics

<u>Feature</u>	<u>SLAV™ Injection Port</u>	<u>Predicate Device Braun SafSite®</u>	<u>Predicate Device Medex Nu-Site™</u>
Intended Use	Intravenous and Blood Administration.	Intravenous and Blood Administration.	Intravenous and Blood Administration.
Disposable Single Patient Use	Yes	Yes	Yes

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Summary of Technological Characteristics continuation...

<u>Feature</u>	<u>SLAV™ Injection Port</u>	<u>Predicate Device Braun SafSite®</u>	<u>Predicate Device Medex Nu-Site™</u>
Flow Rate	310 -350 ml / min.	> 250 ml / min.	> 250 ml / min.
Priming Vol. Required	0.028 ml.	0.30 ml	0.12 ml.
Heparin Lock Injec. Ports	Yes	Yes	Yes
J - Loop Tube Extension	Yes	No	Yes
T - Connector/ Tube Ext.	Yes	No	Yes
IV Administration Sets	Yes	No	No
Multiple Access IV Manifold	Yes	Yes	Yes
Packaging	Blister Pack	Blister Pack	Blister Pack
Sterilization	ETO	Unknown, believed to be ETO	Unknown, believed to be ETO
Non-Pyrogenic	Yes	Yes	Yes
Materials	ABS, Silicone, PVC Polyethylene/Polypropylene	Polycarbonate, Silicone PVC, Polyethylene	ABS, Silicone, PVC Polyethylene
Performance Standards	Unknown	Unkown	Unknown

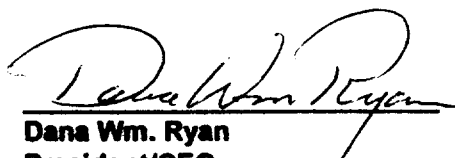
Summary of Performance Data

<u>Test</u>	<u>SLAV™ Injection Port</u>	<u>BRAUN SafSite®</u>	<u>Medex Nu-Site™</u>
Fluid Flow Rate ≥ 150 cc / min.	Passed	Passed	Passed
Ideal Priming Volume less than 0.1 ml	Passed	Failed	Failed
100 Activation's with no leaking or change in performance capabilities	Passed	Passed	Passed

Conclusion

The SLAV™ Injection Port Systems meet the requirements to be considered similar in Technological Characteristics and in Performance to the predicate devices, we believe that the SLAV™ Injection Port Systems are safe and effective and perform as well as or better than the predicate devices. The SLAV™ will be manufactured per specifications and under Good Manufacturing Practices by an ISO 9000 Certified manufacturer to ensure the devices are safe and effective for its intended use.

RyMed Technologies, Inc.



Dana Wm. Ryan
President/CEO