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IX. SUMMARY OF SAFETY AND EFFECTIVENESS

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MANUFACTURER:

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DEVICE NAME:

The EVT[®] Marker Board is an accessory to an image intensified fluoroscopy x-ray system, 21 CFR 892.1650, Class II.

SUBSTANTIAL EQUIVALENCE:

The EVT[®] Marker Board is substantially equivalent to the IZI Medical Products Topographic Marker, (K930752, Class II). The EVT[®] Marker Board is used external to the body. A control box is used to remotely move the position of the markers that are within the marker board. The IZI Medical Products Topographic Markers have adhesive backing which is peeled off and the markers are positioned directly on the body.

DEVICE DESCRIPTION:

The EVT[®] Marker Board is an all-mechanical aid placed external to the body. It consists of two main components, 1) the polycarbonate plate which houses the radiopaque, movable markers, and 2) the control box which is used to remotely move the position of the markers.

INTENDED USE:

The EVT[®] Marker Board is used to identify anatomical landmarks during fluoroscopic procedures.