Based on the predicates given for the safety case pattern of the Generic Patient-Controlled Analgesia (GPCA) system (infusion pump), the instantiated safety case can be developed as follows:

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G1: Operational safety is verified in GPCA system

- S1: Argument over the satisfaction of all specs over GPCA system (undeveloped)

- G2: All operational hazards are mitigated

- S3: Argument over operational hazards

- G3.0: Overinfusion is mitigated

- S4.0: Argument over the applied scenarios of Overinfusion

- G4.0: Overinfusion is mitigated under bolus excessive scenario

- S5.0: Argument over all specs related to bolus excessive scenario

- G5.0: Flow rate control is appropriate for bolus excessive scenario

- S6.0: Argument the appropriateness of flow rate control over properties

- G6.0: Flow rate is less than 90% of the programmed rate setting is appropriate for flow rate control

- S7.0: Argument over the source of the flow rate property definition

- G7.0: FDA standard is appropriate and trustworthy

- Sn1: FDA documentation

- G8.0: Flow rate property definition is sufficient

- Sn2: Engineering analysis

- G3.1: Underinfusion is mitigated

- S4.1: Argument over the applied scenarios of Underinfusion

- G4.1: Underinfusion is mitigated under dose limit exceeded scenario

- S5.1: Argument over all specs related to dose limit exceeded scenario

- G5.1: Dose monitoring system is appropriate for dose limit exceeded scenario

- S6.1: Argument the appropriateness of dose monitoring system over properties

- G6.1: Dose amount within therapeutic level is appropriate for dose monitoring system

- S7.1: Argument over the source of the dose monitoring property definition

- G7.1: Expert opinion is appropriate and trustworthy

- Sn1: Expert testimony

- G8.1: Dose monitoring property definition is sufficient

- Sn2: Clinical study data

- S2: Argument over reliability in all suitable levels of GPCA system (undeveloped)

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### Explanation of Levels:

- \*\*Level 1\*\* (G1) relates to the overall operational safety verification of the GPCA system.

- \*\*Level 2\*\* includes diverse strategies related to operational safety and satisfaction across various specifications under different scenarios.

- \*\*Level 3 and beyond\*\* progressively drill down into specific hazards, their mitigation under particular scenarios, the appropriateness of specific technical specifications, and the verification of those specifications against property definitions.

- Under-developed and various placeholders have been instantiated based on the domain-specific information provided.

- Each level supports a strategy or a set of goals underpinning the primary goal at the higher level.

- The contexts and solutions provide backing information and evidence for the assumptions made at various strategy and goal levels.

This structured format gives a hierarchical view of how goals and strategies are interconnected to ensure the operational safety of the GPCA system, dealing specifically with critical hazards like overinfusion and underinfusion.