To instantiate the Safety Case Pattern for the Generic Patient-Controlled Analgesia (GPCA) system’s operational safety, let's provide domain-specific information to replace the placeholders and develop the undelineated goals and strategies based on the information provided in the domain description. Each goal and strategy are represented in a hierarchical tree structure to illustrate their relationships clearly.

\*\*Instantiated Safety Case for GPCA System\*\*:

```

@Assurance\_case

- G1: Operational safety is verified in GPCA system

- S1: Argument over the satisfaction of all safety requirements in GPCA system (Developed)

- C1: Safety requirements are given by FDA standard and expert opinion

- G2: All operational hazards are mitigated

- S3: Argument over operational hazards

- C2: Operational hazards include Overinfusion and Underinfusion

- G3: Overinfusion is mitigated

- S4: Argument over the applied scenarios of Overinfusion

- C3: Scenarios include Overinfusion due to excessive bolus

- G4: Overinfusion due to excessive bolus is mitigated under nominal operation

- S5: Argument over all safety requirements related to nominal operation scenario

- C4: All related safety requirements vetted by the FDA

- G5: Flow rate sensor spec is appropriate for nominal operation

- S6: Argument the appropriateness of specs over properties

- C5: Properties include triggering of the underinfusion alarm within 15 minutes

- G6: "Flow rate is less than 90% of programmed rate" property is appropriate for nominal operation scenario

- S7: Argument over the source of the property definition

- C6: Source of property definition is FDA standard

- G7: FDA standard is appropriate and trustworthy

- Sn1: FDA compliance documentation

- G8: "Flow rate < 90% of programmed rate" definition is sufficient

- Sn2: Published FDA guidance on infusion pump standards

- G3: Underinfusion is mitigated

- S4: Argument over the applied scenarios of Underinfusion

- C3: Scenarios include Underinfusion due to program rate being too low

- G4: Underinfusion due to program rate too low is mitigated under patient alert scenario

- S5: Argument over all safety requirements related to patient alert scenario

- C4: All related safety requirements vetted by expert opinions

- G5: Low rate alarm spec is appropriate for patient alert scenario

- S6: Argument the appropriateness of specs over properties

- C5: Properties include triggering of the Underinfusion alarm at correct rates

- G6: "Programmed rate too low" property is appropriate for patient alert scenario

- S7: Argument over the source of the property definition

- C6: Source of property definition is expert opinion

- G7: Expert opinion is appropriate and trustworthy

- Sn1: Expert peer reviews

- G8: "Programmed rate too low" definition is sufficient

- Sn2: Expert published papers on safe infusion rates

@End\_Assurance\_case

```

This safety case uses particular examples to explain the chain of reasoning from high-level safety goals to the specifications and properties defined for the GPCA system, validating the mitigation of specified hazards in scenarios with supported material such as FDA standards and expert opinions. Each component has been instantiated from placeholders where necessary with defined strategies, contexts, and evidences linked to appropriate depth levels as prescribed.