DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax:(973) 331-4969 Industry Information: www.fda.gov/oc/industry	07/22/2011 - 08/25/2011* FEI NUMBER 1121308

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: John Kovacevich, Plant Manager

FIRM NAME	STREET ADDRESS
Integra LifeSciences Corp	105 Morgan Ln
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Plainsboro, NJ 08536-3339	Medical Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

Your firm has manufactured Class II (e.g., NeuraGen Nerve Guide, TenoGlide) and Class III (Integra artificial skin products [e.g., Dermal Regeneration Template], Absorable Collagen products) medical devices under the following conditions.

Production and Process Controls (P&PC)

OBSERVATION 1

Buildings are not of suitable design to perform necessary operations.

On June 15, 2009, your firm identified visible mold in the equipment storage area (Room (b) (4) and the closet housing your Deionized Ultra-filtered Water system (Room (b) (4) directly adjacent to your ISO Class 7 Clean Room. The mold was also visibly identified in the Mechanical Room (Room (b) (4) that houses the Water for Injection (WFI) water system.

The third party environmental company, which was hired by your firm to remediate the mold in these areas, identified several mold types in an Industrial Hygiene Report for Mold Exposure dated July 2009. Mold types identified in the results of this report include Aspergillus/Penicillium-like, Ascospores, Basidiospores, Stachybotrys, Ulocladium and other/unidentified. This report went on to state that employees in these areas are exposed to mold, and that the presence of the mold could compromise the integrity of the final product manufactured at the facility.

Your firm continued to identify mold throughout your 105 Morgan Lane manufacturing facility from June 15, 2009 to the present. The mold assessment and remediation activities are documented by your firm in Quality Plans (QP), and you have generated seventeen QPs to date. During that time your firm continued to manufacture, release and distribute approximately (b) (4) lots of various Integra products and products contract manufactured for your customers.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Loretta Nemchik, Investigator Loretta Nemchik Meredith L. Sheridan, Investigator Meredith Sheridan	08/25/2011

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax:(973) 331-4969 Industry Information: www.fda.gov/oc/industry	07/22/2011 - 08/25/2011* FEI NUMBER 1121308

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: John Kovacevich, Plant Manager

FIRM NAME	STREET ADDRESS
Integra LifeSciences Corp	105 Morgan Ln
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Plainsboro, NJ 08536-3339	Medical Device Manufacturer

OBSERVATION 2

A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.

A. CAPA 12307 was initiated to review the adequacy of cleaning validations and cleaning procedures associated with multiple pieces of equipment used in the manufacturing of Integra skin and medical products. As a result of this review a document was submitted to firm management on 4/30/10 that identifies deficiencies associated with multiple cleaning validations. Although a re-evaluation of the cleaning program by an outside contractor was done in April 2011 and a risk assessment was done by your firm in May 2011, your firm continued to use this equipment before these activities were completed.

For example, the review identified that the cleaning validation for the Integra Mixing Tanks ((b) (4) was inadequate because the validation states that the (b) (4) used in the cleaning procedure completely accesses all inner areas of the tanks even though no (b) (4) area coverage test was done. The Integra Mixing Tanks were used in the manufacture of (b) (4) lot #105000210455 on 2/23/11 and (b) (4) lot #105000209549 on 2/14/11. (b) (4) ot #105000210455 was used in Integra Bilayer Matrix Wound Dressing lot #s 105A00212334, 105B00212334, 105A00212335 and 105B00212335; and Integra Meshed Bilayer Matrix Wound Dressing lot #s 105A00212336 and 105A00212337. (b) (4) lot #105000209549 was used in Integra Matrix Wound Dressing lot #s 105A00210458, 105B00210458, 105A00210652, 105B00210652, 105A00210653 and 105B00210653; and Integra Meshed Bilayer Matrix Wound Dressing lot #105A00210459. As of the temporary closure of the Integra Suite in July of 2011 for remediation/renovation, no new cleaning validation for the Integra Mixing Tanks has been performed.

B. Your firm's validation for the "WFI Distribution System In-line (b) (4) Analyzer and (b) (4) ", which is used to monitor TOC, pH, flow and conductivity on your WFI water system, does not include a Performance Qualification. Your firm explained this is because the full function of the instrument is to transmit information to a (b) (4) recorder. The validation for the (b) (4) recorder has not been executed to date. Data from this unvalidated recorder was collected and analyzed from 1/2011-4/2011 on a memo dated 4/21/2011, to support the investigation and release of quarantined products in Non Conforming Report #0126.

This is a repeat observation from the previous establishment inspection.

OBSERVATION 3

Procedures to control environmental conditions have not been adequately established.

A. Your environmental control procedures as written allow for an unclear amount of re-sampling to be conducted when an Out of Specification (OOS) result is received. For Example:

1) SOP G-631, Rev. 16, Microbiological and Chemical Analysis of Process Water, under section 5.5.3 states any OOS result is to be re-sampled. The procedure goes on to state (b) (4) is required to confirm the first re-sampling results,

and an Out of Specification investigation is to be opened under SOP MB-026, Rev. 7, Microbiology Out of Specification Investigation Procedure. Attachment 3 of MB-026, Rev. 7 is the flow chart to follow for LAL-Water OOS which states (b) (4) more re-samples are to be collected.

2) SOP MB-001, Rev. 23, Microbiological Analysis of WFI and Pure Steam, states an alert level result is to be (b) (4) re-sampled, then an OOS investigation is initiated under MB-026, Rev. 7. The procedure goes on to state to collect a re-sample of the affected port for (b) (4) then initiate an OOS investigation per SOP MB-026, Rev. 7. Attachment 1 of MB-026, Rev. 7 is the flow chart for Environmental Monitoring which states to "Resample as per SOP".

3) SOP 601, Rev. 20, Environmental Monitoring Plan for the Integra Manufacturing Area, states when results exceed alert levels the site is to be re-sampled (b) (4) Then an investigation is to be opened per SOP MB-026, Rev. 7. Attachment 1 of MB-026, Rev. 7 is the flow chart for Environmental Monitoring which states to "Resample as per SOP".

4) SOP G-523, Rev. 30, Microbiological Monitoring of the Medical Products Manufacturing Clean Areas, states results exceeding alert levels are to be documented on an Alert/Action Notification form which is Attachment 9 of MB-026, Rev. 7. The form allows for (b) (4) re-sampling results. The procedure then states to resample the site (b) (4) if the re-samples exceed alert levels then an investigation is to be opened under MB-026, Rev 7. Attachment 1 of MB-026, Rev. 7 is the flow chart for Environmental Monitoring, which states to "Resample as per SOP".

B. Your firm's Cleanroom Maintenance Procedure (SOP #823, Rev 3) requires a HEPA filter velocity verification to be done (b) (4) for the Integra Suite, the site of the final manufacturing steps of the Integra artificial skin products. This requirement became effective 5/4/11. Although your Integra Suite was operating in May 2011 and June 2011, the HEPA filter velocity verification was not performed. The Integra Suite was shutdown in July 2011 for remediation/renovation.

OBSERVATION 4

Procedures that define the responsibility for review and the authority for the disposition of nonconforming product have not been adequately established.

A. Your procedure, SOP G-539, Rev. 15, 16, 17, 18, 19 and 20, Nonconforming Material and Processes, states an investigation and root cause analysis is to be conducted to determine the root cause of the problem. The procedure goes on to reference SOP-QA-041, Rev.1, Root Cause Analysis Investigation. Under section 5.1 of SOP QA-041 it states that information should be collected consisting of conditions before, during and after the occurrence, including environmental factors. Your firm identified mold contamination in several areas of your facility beginning in June 2009 to the present, however this existing environmental condition is not considered in the investigation documentation of the Non Conforming Reports (NCR) #2218 dated 11/1/2010, 2014 dated 3/23/2010 and 0126 dated 4/19/2011, which were initiated when environmental monitoring results exceeded alert/action limits for mold.

B. NCR#2044 refers to the Water for Injection (WFI) water system sanitization loop failure. The dates listed on the NCR are listed as 4/30/2010, 5/01/2010, and 5/02/2010. The investigation of the occurrence does not including any supporting documentation as required in procedure SOP G-539, Rev. 15 Section 5.3.2.2. Review of the chart paper from the temperature recorder on the WFI system for the time frame revealed that the chart paper became jammed and did not record

the sanitization loop on 4/28/2010, another paper jam occurred on 4/29/2010, and a third paper jam and a possible power outage occurred on 4/30/2010, during the sanitization loop. Due to the incorrect dates recorded on the NCR not all lots were adequately quarantined. For example, the quarantine lots listed in the NCR does not include Finished Good Lot#B00179881, Master Graft Matrix which was made from (b) (4) ot#105000177800, which was manufactured on 4/30/2010.

1) NCR#2044 refers to the Water for Injection (WFI) water system sanitization loop failure on 4/30/2010, 5/01/2010, and 5/02/2010. NCR#2084 refers to the Water for Injection (WFI) water system sanitization loop failure on 6/08/2010, 6/09/2010, and 6/10/2010. Though the investigation was assigned to the same individual, and the NCRs share the exact same background information, investigation information and Product/Process disposition and justification, they are written in two different handwritings and have two different root causes, neither of which contains supporting documentation as required in SOP-539 Rev. 15 and 16.

C. SOP-539, Rev. 20, in section 4.6 states NCRS are to be completed within (b) (4) business days of initiation. According to the NCR index provided by your firm over twenty NCRs are currently overdue.

OBSERVATION 5

Schedules for the adjustment, cleaning, and other maintenance of equipment have not been adequately established.

Although your current Preventive Maintenance Schedule for Equipment and Systems procedure (#432, Rev 19, Effective 4/3/11) identifies a grace period for (b) (4) preventive maintenance activities, it does not identify any grace period for (b) (4) activities. The Cleanroom Maintenance Procedure in effect at the initiation of this inspection (#823, Rev 3) requires (b)( ) PM for the Medical Manufacturing area. (b) (4) inspections were due on 5/25/11, 6/8/11 and 8/4/11 but were not done until 5/31/11 (6 days beyond due date), 6/19/11 (11 days beyond due date) and 8/8/11 (4 days beyond due date) respectively.

Corrective & Preventive Actions

OBSERVATION 6

Complaints representing events that are MDR reportable were not promptly reviewed, evaluated, and investigated by a designated individual.

Specifically, of the approximately 19 complaints containing MDR reportable events reviewed during this inspection 5 were not promptly investigated by your manufacturing site.

For example -

1) Complaint PR ID 34424 was received on 12/01/10 and a request for an investigation was made on 12/6/10. The complaint states that the packaging of a medical device (Bilayer Matrix Wound Dressing, lot #105A00189537) manufactured by your firm contained brown stains and that a tiny hole was found in the inner package compromising the integrity and sterility of

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax:(973) 331-4969 Industry Information: www.fda.gov/oc/industry	07/22/2011 - 08/25/2011* FEI NUMBER 1121308

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
TO: John Kovacevich, Plant Manager	
FIRM NAME Integra LifeSciences Corp	STREET ADDRESS 105 Morgan Ln
CITY, STATE, ZIP CODE, COUNTRY Plainsboro, NJ 08536-3339	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer

the product. The device was not used. A Medical Device Report (MDR #1121308-2010-00031) was filed on 12/29/10. Although the Investigation Plan (DHR review, customer comment review, inspect returned product, review complaint trend) was prepared on 12/7/10, no investigation was done by your firm until 1/19/11which was approximately 49 days after complaint receipt and 44 days after the request for an investigation was made.

2) Complaint PR ID 45523 was received on 5/26/11 and a request for an investigation was made on 5/27/11. The complaint states that a medical device (NeuraGen Nerve Guide, lot #1090766) manufactured by your firm was used in a patient. The patient later experienced a foreign body reaction at the implantation site. A Medical Device Report (MDR #1121308-2011-00018) was filed on 6/15/11. Although the Investigation Plan (DHR review, customer comment review, inspect returned product, review complaint trend) was prepared on 6/1/11, no investigation was done by your firm until 7/8/11 which was approximately 43 days after complaint receipt and 42 days after the request for an investigation was made.

3) Complaint PR ID 46035 was received on 6/3/11 and a request for an investigation was made on 6/7/11. The complaint states that a medical device (TenoGlide, lot #105A00193691) manufactured by your firm was used in a patient during a removal of a ganglion cyst. The patient later required revision surgery to remove a soft tissue nodule that had formed at the revision site. A Medical Device Report (MDR #1121308-2011-00019) was filed on 6/21/11. Although the Investigation Plan (DHR review, customer comment review, inspect returned product, review complaint trend) was prepared on 6/9/11, no investigation was done by your firm until 7/22/11 which was approximately 49 days after complaint receipt and 45 days after the request for an investigation was made.

4) Complaint PR ID 46152 was received on 6/9/11 and a request for an investigation was made on the same day. The complaint states that the packaging of a medical device (Integra Dermal Regeneration Template, lot # 105C00202206) manufactured by your firm contained stains and that a crack was found on the inner package compromising the integrity and sterility of the product. The device was not used. A Medical Device Report (MDR #1121308-2011-00022) was filed on 6/28/11 Although the Investigation Plan (DHR review, customer comment review, inspect returned product, review complaint trend) was prepared on 6/9/11, no investigation was done by your firm until 7/21/11 which was approximately 42 days after complaint receipt and the request for an investigation was made.

5) Complaint PR ID 45844 was received on 5/24/11 and a request for an investigation was made on 6/7/11. The complaint states that the inside packaging of a medical device (Integra Dermal Regeneration Template, lot #105B00165833) manufactured by your firm was stained brown where it should have been sterile. The device was not used. A Medical Device Report (MDR #1121308-2011-00026) was filed on 7/5/11. Although the Investigation Plan (DHR review, customer comment review, inspect returned product, review complaint trend) was prepared on 6/9/11, no investigation was done by your firm until 7/21/11 which was approximately 58 days after complaint receipt and 44 days after the request for an investigation was made.

This is a repeat observation from the previous establishment inspection.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Loretta Nemchik, Investigator Meredith L. Sheridan, Investigator MLS	DATE ISSUED 08/25/2011

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax:(973) 331-4969 Industry Information: www.fda.gov/oc/industry	07/22/2011 - 08/25/2011* FEI NUMBER 1121308

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: John Kovacevich, Plant Manager

FIRM NAME	STREET ADDRESS
Integra LifeSciences Corp	105 Morgan Ln
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Plainsboro, NJ 08536-3339	Medical Device Manufacturer

OBSERVATION 7

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

For example, of the approximately 19 complaints classified as MDR reportable events reviewed during this inspection, 3 events were not reported to FDA within 30 days of receipt.

Specifically-

1) Integra LifeSciences (ILS) was made aware of Complaint PR ID 22089 on 4/22/10. The complaint states that when the sales representative checked the stock mold was found on the foil package containing Integra Dermal Regeneration Template, lot #105BZ0143276. The product was not used on a patient. The complaint was evaluated for MDR reporting on 4/22/10 and a MedWatch (MDR 1121308-2010-00013) notification was sent to FDA on 5/27/10, approximately 35 days after ILS was made aware of the complaint.

2) ILS was made aware of Complaint PR ID 24121 on 5/31/10. The complaint states that the foil package containing Integra Dermal Regeneration Template, lot #105BZ0126071, appeared to be leaking and the integrity of the product was in question. The product was not used on a patient. The complaint was evaluated for MDR reporting on 5/31/10 and a MedWatch (MDR 1121308-2010-00016) notification was sent to FDA on 7/28/10, approximately 58 days after ILS was made aware of the complaint.

3) Information pertaining to Complaint PR ID 45844 was provided to an employee (sales representative) of ILS on 5/24/11. The complaint states that the inside packaging containing Integra Dermal Regeneration Template, lot #105B00165833, was stained where it should have been sterile. The product was not used on a patient. The complaint was forwarded to the ILS Complaint Department and received on 6/2/11. The complaint was evaluated for MDR reporting on 6/3/11 and according to information provided by the ILS Complaint Manager it was decided that the event was not reportable. According to the ILS Complaint Manager the complaint was re-evaluated on 6/27/11 and was determined to be reportable. A MedWatch (MDR 1121308-2011-00026) notification was then sent to FDA on 7/5/11, approximately 42 days after ILS was made aware of the complaint.

This is a repeat observation from the previous establishment inspection.

OBSERVATION 8

Procedures for corrective and preventive action have not been adequately established.

A. Your firm's CAPA procedure is not adequately defined. Specifically -

1) Your firm's CAPA procedure allows corrective and preventive actions to remain uninitiated for prolonged periods of time.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Loretta Nemchik, Investigator Meredith L. Sheridan, Investigator	08/25/2011

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax:(973) 331-4969 Industry Information: www.fda.gov/oc/industry	07/22/2011 - 08/25/2011* FEI NUMBER 1121308

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: John Kovacevich, Plant Manager

FIRM NAME	STREET ADDRESS
Integra LifeSciences Corp	105 Morgan Ln
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Plainsboro, NJ 08536-3339	Medical Device Manufacturer

a) For example, CAPA 12307 was opened on 10/8/09 as a preventive action to identify gaps in your firm's previously executed equipment cleaning validations. A Cleaning Validation Gap Analysis status report identifying deficiencies in these cleaning validations was issued in April 2010. This report recommended that a Master Cleaning Program be written and that this program include activities such as establishing dirty equipment and clean equipment hold times, sampling rationales, acceptable residue limits and conducting recovery tests, activities which were lacking in previously executed cleaning validations. On 2/2/11, 10 months after the cleaning validation deficiencies were identified, another CAPA, 37944, was opened to create a Cleaning Validation Master Plan (CVMP). A risk analysis (5/11) and a cleaning program re-evaluation (4/11) were also conducted as part of CAPA 37944. The CVMP which contains requirements for establishment of dirty equipment and clean equipment hold times, worst-case residue assessment and rinse recovery tests was approved in July 2011, more than 15 months after cleaning validation deficiencies were identified.

b) For example, CAPA 7242 was opened on 6/22/09 to investigate potential sources of foreign material (particulates) in final products. The particulates were analyzed and potential sources of the particulates (materials and equipment) were identified on 3/19/10. A risk analysis identifying the potential effect of the particulates on patients was also performed in March 2010 under CAPA 7242. On 4/7/10 another CAPA, 21280, was opened to identify potential sources of particulates from equipment used in the manufacturing process and to recommend preventive actions that needed to be taken with the equipment to prevent these particulates from occurring. On 4/11/11 another CAPA, 42697, was opened to implement the preventive actions recommended by CAPA 21280. As of the review of CAPA 42697 on or about 7/26/11, more than 16 months after equipment was identified as a potential source of the particulates, there was no documentation to indicate that these preventive actions have been implemented.

B. Your firm's CAPA procedure (QA-051) was not adequately implemented.

1) For example, your firm's root cause analysis for CAPA 12498 was not adequate. Specifically, the investigation of CAPA 12498 did not consider the mold discovered in your facility in June 2009 as a possible cause of the viable environmental excursions in the Integra Suite.

2) For example, your procedure requires an interim report for an extension of a CAPA. However, the interim report was not done for CAPA 26087 and CAPA 21280 prior to the due date. Specifically, CAPA 26087 was due on 11/8/10 but the interim report seeking approval to extend the due date was not filed and approved until 11/11/10. CAPA 21280 was due on 8/16/10 but interim report #1 seeking approval to extend the due date was not filed and approved until 9/22/10 and interim report #2 seeking approval to extend the due date from 3/30/11 was not filed until 4/5/11. Additionally, CAPA 12498 after 3 extensions was due on 4/1/11 but was not closed until mid-April 2011.

3) For example, your firm's Quality Plans (QP) are not consistently captured in your CAPA system even though your firm's CAPA procedure states that the CAPA procedure applies to preventing and correcting non-conformities relating to production processes and quality system issues. For example, QP-154 issued on 5/5/11 is the QP for the (b) (4) Lyophilizer repair. The (b) (4) Lyophilizer is used in the manufacture of the Integra (b) (4) Although CAPA 19486 was opened on 3/3/10 to investigate and resolve (b) (4) Lyophilizer issues there is no reference to QP-154 in this CAPA. For example, QP-147 issued on 3/15/11 is the QP for the replacement of (b) (4) gauges in the Integra Suite

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Loretta Nemchik, Investigator Meredith L. Sheridan, Investigator	08/25/2011

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax:(973) 331-4969 Industry Information: www.fda.gov/oc/industry	07/22/2011 - 08/25/2011* FEI NUMBER 1121308

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: John Kovacevich, Plant Manager

FIRM NAME	STREET ADDRESS
Integra LifeSciences Corp	105 Morgan Ln
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Plainsboro, NJ 08536-3339	Medical Device Manufacturer

where Integra (b) (4) is manufactured. Although CAPA 37211 was opened on 1/21/11 for the Integra Suite HVAC mechanical, control and room conditioning monitoring mitigation there is no reference to QP-147 in this CAPA.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Loretta Nemchik, Investigator Loretta Nemchik 8/25/11

Meredith L. Sheridan, Investigator Meredith Sheridan 8/25/11

DATE ISSUED 08/25/2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax:(973) 331-4969 Industry Information: www.fda.gov/oc/industry	07/22/2011 - 08/25/2011* FEI NUMBER 1121308

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: John Kovacevich, Plant Manager

FIRM NAME	STREET ADDRESS
Integra LifeSciences Corp	105 Morgan Ln
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Plainsboro, NJ 08536-3339	Medical Device Manufacturer

Observation Annotations

Observation 1:	Promised to correct.	Observation 2:	Promised to correct.
Observation 3:	Promised to correct.	Observation 4:	Promised to correct.
Observation 5:	Promised to correct.	Observation 6:	Promised to correct.
Observation 7:	Promised to correct.	Observation 8:	Promised to correct.

*** DATES OF INSPECTION:**
07/22/2011(Fri), 07/25/2011(Mon), 07/26/2011(Tue), 07/28/2011(Thu), 08/01/2011(Mon), 08/02/2011(Tue), 08/03/2011(Wed), 08/05/2011(Fri), 08/08/2011(Mon), 08/09/2011(Tue), 08/10/2011(Wed), 08/16/2011(Tue), 08/17/2011(Wed), 08/18/2011(Thu), 08/19/2011(Fri), 08/24/2011(Wed), 08/25/2011(Thu)

	EMPLOYEE(S) SIGNATURE	DATE ISSUED
SEE REVERSE OF THIS PAGE	Loretta Nemchik, Investigator 8/25/11 Meredith L. Sheridan, Investigator 8/25/11	08/25/2011