

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		Complete and Return Only the Original Form to: Please do not mail the instruction pages with your form. Food and Drug Administration Center for Devices & Radiological Health, HFZ-308 9200 Corporate Blvd., Rockville, MD 20850-4015		Form Approved: OMB No. 0910-0387 Expiration Date: April 30, 2008		1. TODAY'S DATE (mm/dd/yyyy) 09/25/2006	
<b>DEVICE LISTING</b>							
<b>NOTE:</b> This form is authorized by Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360). Failure to report this information is a violation of Section 301(p) of the Act (21 U.S.C. 331(p)). Persons who violate this provision may, if convicted, be subject to a fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2), (21 U.S.C. 331(q)(2)) and may be a violation of 18 U.S.C. 1001. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.							
2. OWNER/OPERATOR NUMBER 9082994				4. REGISTRATION NUMBER 3005831677			
3. OWNER/OPERATOR NAME (Business name) B&L Biotech Co., Ltd.				5. ESTABLISHMENT NAME (Business name) B&L Biotech Co., Ltd.			
NUMBER AND STREET #502, Gungjeon Tower, 723-3, Gojan-dong, Danwon-gu				NUMBER AND STREET #502, Gungjeon Tower, 723-3, Gojan-dong, Danwon-gu			
CITY Ansan-city		STATE		CITY Ansan-city		STATE	
FOREIGN STATE Kyungki-do,		POSTAL CODE		FOREIGN STATE Kyungki-do,		POSTAL CODE	
COUNTRY KOREA				COUNTRY KOREA			
6. LISTING INFORMATION: Number of product codes you are going to list for this establishment:				1			
REASON FOR LISTING: <input type="checkbox"/> New Listing <input checked="" type="checkbox"/> Update to Device Already Listed <input type="checkbox"/> Delete Listing				REASON FOR LISTING: <input type="checkbox"/> New Listing <input type="checkbox"/> Update to Device Already Listed <input type="checkbox"/> Delete Listing			
PRODUCT CODE EKR		PMA NUMBER		PRODUCT CODE		PMA NUMBER	
510(k) NUMBER K060347				510(k) NUMBER			
CLASSIFICATION NAME Plugger, root canal, endodontic				CLASSIFICATION NAME			
PROPRIETARY NAME B&L Beta Model WL-B1 and B&L Alpha II Model CL-A1				PROPRIETARY NAME			
COMMON OR USUAL NAME Heated Gutta Percha System				COMMON OR USUAL NAME			
PREVIOUS LISTING NUMBER E428728		LISTING NUMBER E527395		PREVIOUS LISTING NUMBER		LISTING NUMBER E527396	
<input type="checkbox"/> Contract Manufacturer		<input checked="" type="checkbox"/> Manufacturer		<input type="checkbox"/> Contract Manufacturer		<input type="checkbox"/> Manufacturer	
<input type="checkbox"/> Contract Sterilizer		<input type="checkbox"/> Remanufacturer		<input type="checkbox"/> Contract Sterilizer		<input type="checkbox"/> Remanufacturer	
<input type="checkbox"/> Foreign Exporter		<input type="checkbox"/> Repackager/Relabeler		<input type="checkbox"/> Foreign Exporter		<input type="checkbox"/> Repackager/Relabeler	
		<input type="checkbox"/> Reprocessor of Single Use Devices				<input type="checkbox"/> Reprocessor of Single-use device	
		<input type="checkbox"/> Specification Developer				<input type="checkbox"/> Specification Developer	
		<input type="checkbox"/> U.S. Manufacturer of Export Only Devices				<input type="checkbox"/> U.S. Manufacturer of Export Only Devices	
REASON FOR LISTING: <input type="checkbox"/> New Listing <input type="checkbox"/> Update to Device Already Listed <input type="checkbox"/> Delete Listing				REASON FOR LISTING: <input type="checkbox"/> New Listing <input type="checkbox"/> Update to Device Already Listed <input type="checkbox"/> Delete Listing			
PRODUCT CODE		PMA NUMBER		PRODUCT CODE		PMA NUMBER	
510(k) NUMBER				510(k) NUMBER			
CLASSIFICATION NAME				CLASSIFICATION NAME			
PROPRIETARY NAME				PROPRIETARY NAME			
COMMON OR USUAL NAME				COMMON OR USUAL NAME			
PREVIOUS LISTING NUMBER		LISTING NUMBER E527397		PREVIOUS LISTING NUMBER		LISTING NUMBER E527398	
<input type="checkbox"/> Contract Manufacturer		<input type="checkbox"/> Manufacturer		<input type="checkbox"/> Contract Manufacturer		<input type="checkbox"/> Manufacturer	
<input type="checkbox"/> Contract Sterilizer		<input type="checkbox"/> Remanufacturer		<input type="checkbox"/> Contract Sterilizer		<input type="checkbox"/> Remanufacturer	
<input type="checkbox"/> Foreign Exporter		<input type="checkbox"/> Repackager/Relabeler		<input type="checkbox"/> Foreign Exporter		<input type="checkbox"/> Repackager/Relabeler	
		<input type="checkbox"/> Reprocessor of Single Use Devices				<input type="checkbox"/> Reprocessor of Single Use Devices	
		<input type="checkbox"/> Specification Developer				<input type="checkbox"/> Specification Developer	
		<input type="checkbox"/> U.S. Manufacturer of Export Only Devices				<input type="checkbox"/> U.S. Manufacturer of Export Only Devices	
7. SIGNATURE OF OFFICIAL CORRESPONDENT				8. TYPED OR PRINTED NAME Daniel Kamm		TITLE Official Correspondent/US Agent	